

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-K/A  
Amendment No. 1**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38311

**Denali Therapeutics Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

46-3872213  
(I.R.S. Employer  
Identification No.)

151 Oyster Point Blvd., 2<sup>nd</sup> Floor  
South San Francisco, CA, 94080  
(Address of principal executive offices and zip code)

(650) 866-8548  
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u> Common stock, par value \$0.01 per share	<u>Name of each exchange on which registered</u> The NASDAQ Global Select Market
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Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of common stock on December 8, 2017 as reported by the NASDAQ Global Select Market on such date was approximately \$628.4 million. The registrant has elected to use December 8, 2017, which was the initial trading date on the NASDAQ Global Select Market, as the calculation date because on June 30, 2017, the registrant was a privately held company. Shares of the registrant's common stock held by each executive officer, director and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of outstanding shares of the registrant's common stock as of March 12, 2018 was 94,429,245.

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the registrant's Definitive Proxy Statement relating to the registrant's 2018 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such Definitive Proxy Statement was filed with the Securities and Exchange Commission within 120 days after the end of the registrant's 2017 fiscal year ended December 31, 2017.

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## EXPLANATORY NOTE

Denali Therapeutics Inc. (the “Company”) is filing this Amendment No. 1 on Form 10-K/A (“Amendment”) to amend its Annual Report on Form 10-K for the year ended December 31, 2017 (the “Form 10-K”), which was originally filed with the Securities and Exchange Commission on March 19, 2018. The purpose of this Amendment is to refile Exhibit 10.16, which was originally filed with the Form 10-K, with revised redactions in response to comments received from the staff of the Securities and Exchange Commission on the confidential treatment request filed by the Company with respect to Exhibit 10.16.

This Amendment speaks as of the original filing date and does not reflect events occurring after the filing of the Form 10-K or modify or update disclosures that may be affected by subsequent events. No revisions are being made to the Company’s financial statements or any other disclosure contained in the Form 10-K.

This Amendment is an exhibit-only filing. Except for the changes to Exhibit 10.16, this Amendment does not otherwise update any exhibits as originally filed or previously amended.

In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), new certifications by the Company’s principal executive officer and principal financial officer are filed herewith as exhibits to this Amendment pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act. The Company is not including certifications pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) as no financial statements are being filed with this Amendment.

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**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this report:

1. Financial Statements

The consolidated financial statements of the Company were previously submitted with the original filing of this Form 10-K.

2. Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits

The documents listed in the Exhibit Index are incorporated by reference or are filed with this report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

**EXHIBIT INDEX**

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Number	Filing Date
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant.</a>	8-K	001-38311	3.1	12/12/2017
3.2	<a href="#">Amended and Restated Bylaws of the Registrant.</a>	8-K	001-38311	3.2	12/12/2017
4.1	<a href="#">Investors' Rights Agreement among the Registrant and certain of its stockholders, dated May 8, 2015, as amended on June 4, 2015, July 22, 2015 and June 22, 2016.</a>	S-1	333-221522	4.1	11/13/2017
4.2	<a href="#">Specimen common stock certificate of the Registrant.</a>	S-1/A	333-221522	4.2	11/27/2017
10.1+	<a href="#">Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.</a>	S-1/A	333-221522	10.1	11/27/2017
10.2+	<a href="#">2015 Stock Incentive Plan, as amended, and forms of agreement thereunder.</a>	S-1	333-221522	10.2	11/13/2017
10.3+	<a href="#">2017 Equity Incentive Plan and forms of agreements thereunder.</a>	S-1/A	333-221522	10.3	11/27/2017
10.4+	<a href="#">2017 Employee Stock Purchase Plan and form of agreement thereunder.</a>	S-1/A	333-221522	10.4	12/7/2017
10.5+	<a href="#">Offer Letter between the Registrant and Ryan J. Watts, Ph.D., dated November 10, 2017.</a>	S-1	333-221522	10.5	11/13/2017
10.6+	<a href="#">Offer Letter between the Registrant and Alexander O. Schuth, M.D., dated November 10, 2017.</a>	S-1	333-221522	10.6	11/13/2017
10.7+	<a href="#">Offer Letter between the Registrant and Steve E. Krognes, dated November 10, 2017.</a>	S-1	333-221522	10.7	11/13/2017
10.8+	<a href="#">Offer Letter between the Registrant and Carole Ho, M.D., dated November 10, 2017.</a>	S-1	333-221522	10.8	11/13/2017
10.9	<a href="#">Lease Agreement between the Registrant and HCP Oyster Point III LLC, dated September 24, 2015.</a>	S-1	333-221522	10.9	11/13/2017
10.10Ü	<a href="#">Exclusive License Agreement between the Registrant and Genentech, Inc., dated June 17, 2016.</a>	S-1	333-221522	10.10	11/13/2017
10.11Ü	<a href="#">License and Collaboration Agreement between the Registrant, F-star Gamma Limited, f-star Biotechnologische Forschungs-und Entwicklungsges m.b.H. and F-star Biotechnology Limited, dated August 24, 2016.</a>	S-1	333-221522	10.11	11/13/2017
10.12Ü	<a href="#">Development and Manufacturing Services Agreement between the Registrant and Lonza Sales AG, dated September 6, 2017, as amended by Amendment No. 1 on October 18, 2017.</a>	S-1	333-221522	10.12	11/13/2017
10.12.1#	<a href="#">Amendment No. 2 to Development and Manufacturing Services Agreement between the Registrant and Lonza Sales AG, dated September 6, 2017, as amended by Amendment No. 1 on October 18, 2017, dated January 18, 2018.</a>	10-K	001-38311	10.12.1	3/19/2018
10.13+	<a href="#">Key Executive Change in Control and Severance Plan.</a>	S-1	333-221522	10.13	11/13/2017
10.14+	<a href="#">Executive Incentive Compensation Plan.</a>	S-1	333-221522	10.14	11/13/2017
10.15+	<a href="#">Outside Director Compensation Policy.</a>	S-1	333-221522	10.15	11/13/2017
10.16#	<a href="#">Option and Collaboration Agreement between the Registrant and Takeda Pharmaceutical Company Limited, dated January 3, 2018.</a>				
10.17	<a href="#">Common Stock Purchase Agreement between the Registrant and Takeda Pharmaceutical Company Limited, dated January 3, 2018.</a>	10-K	001-38311	10.17	3/19/2018
10.18	<a href="#">Standstill and Stock Restriction Agreement between the Registrant and Takeda Pharmaceutical Company Limited, dated February 23, 2018.</a>	10-K	001-38311	10.18	3/19/2018
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm.</a>	10-K	001-38311	23.1	3/19/2018
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.</a>	10-K	001-38311	31.1	3/19/2018
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.</a>	10-K	001-38311	31.2	3/19/2018
31.3	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.</a>				
31.4	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.</a>				
32.1^	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.				
32.2^	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.				

- Ü Portions of the exhibit have been omitted pursuant to an order granted by the Securities and Exchange Commission for confidential treatment.
- # Portions of this exhibit have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.
- + Indicates management contract or compensatory plan.
- ^ Previously furnished with the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 19, 2018. The information in this exhibit is deemed furnished and not filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the hereof, irrespective of any general incorporation language contained in such filing.

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**ITEM 16. FORM 10-K SUMMARY**

None.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to its Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: July 13, 2018

**DENALI THERAPEUTICS INC.**

By: /s/ Ryan J. Watts

Ryan J. Watts, Ph.D.

President and Chief Executive Officer

SPECIFIC TERMS IN THIS EXHIBIT HAVE BEEN REDACTED BECAUSE CONFIDENTIAL TREATMENT FOR THOSE TERMS HAS BEEN REQUESTED. THE REDACTED MATERIAL HAS BEEN SEPARATELY FILED WITH THE SECURITIES AND EXCHANGE COMMISSION, AND THE TERMS HAVE BEEN MARKED AT THE APPROPRIATE PLACE WITH THREE ASTERISKS [\*\*\*].

**OPTION AND COLLABORATION AGREEMENT**

between

**DENALI THERAPEUTICS INC.**

and

**TAKEDA PHARMACEUTICAL COMPANY LIMITED**



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## OPTION AND COLLABORATION AGREEMENT

This Option and Collaboration Agreement (the “**Agreement**”) is made and entered into effective as of January 3, 2018 (the “**Execution Date**”) by and between Denali Therapeutics, Inc., a Delaware corporation (“**Denali**”), and Takeda Pharmaceutical Company Limited, a corporation organized under the laws of Japan (“**Takeda**”). Denali and Takeda are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

### RECITALS

**WHEREAS**, Denali has developed the ATV Platform (as defined herein) and certain Biologics and Products (each, as defined herein) and Controls (as defined herein) certain intellectual property and other rights with respect to such ATV Platform, Biologics and Products in the Territory (as defined herein);

**WHEREAS**, the Parties wish to collaborate in the research and development of Biologics Directed (as defined herein) to Designated Targets (as defined herein) and Denali wishes to grant to Takeda an exclusive option to obtain a license under Denali’s intellectual property with respect to such Biologics Directed to such Designated Targets, and Takeda wishes to obtain such option, for purposes of developing, manufacturing and commercializing Optioned Products (as defined herein) in the Territory, in each case in accordance with the terms and conditions set forth below; and

**WHEREAS**, on even date herewith, Denali and Takeda (or one of its Affiliates) are entering into a stock purchase agreement (“**Stock Purchase Agreement**”) providing for Takeda’s (or one of its Affiliate’s) purchase of stock of Denali, all in accordance with the terms and conditions set forth in such Stock Purchase Agreement.

**NOW, THEREFORE**, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

### ARTICLE 1 DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

**1.1 “Acceptance”** of an IND shall be deemed to have occurred: (a) subject to subsection (b), in the United States and any other applicable country or regulatory jurisdiction, on the date of expiration of any required waiting period following the filing of such IND; *provided* that, if prior to the expiration of such required waiting period, the applicable Regulatory Authority notifies the sponsor of such IND that a clinical study may not begin upon the expiration of such required waiting period, then “Acceptance” shall be deemed to occur as of the date a clinical study may legally begin; and (b) if required in a particular country or regulatory jurisdiction (including the United States and any such other applicable country or regulatory

Confidential

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jurisdiction in the event such approval becomes required therefor during the Term due to any change in Applicable Law), the date of receipt of any required approval from the applicable Regulatory Authority to conduct a clinical study; in each case whichever occurs first.

**1.2 “Accounting Standards”** means, with respect to Denali, the United States Generally Accepted Accounting Principles, and, with respect to Takeda, the International Financial Reporting Standards, in each case, as consistently applied.

**1.3 “Acquisition”** means, with respect to a Party, an acquisition by such Party of a Third Party (whether by merger or acquisition of all or substantially all of the stock or of all or substantially all of the assets of a Third Party or of any operating or business division of a Third Party or similar transaction), other than a Change in Control of the Party.

**1.4 “Additional Development Costs”** means those Out-of-Pocket Costs and FTE Costs incurred by the Proposing Party in performing the relevant Additional Development Activities, which costs shall be determined using the same manner of calculating Development Costs and Allowable Expenses as if such Additional Development Activities had been incorporated into the Development Plan.

**1.5 “Affiliate”** means, with respect to a Person, any other Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such Person. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that, in such case, such lower percentage shall be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management or policies of such entity.

**1.6 “Allowable Expenses”** means, with respect to a Collaboration Program for which Denali has not exercised the Denali Worldwide Royalty Option, all FTE Costs and Out-of-Pocket Costs incurred by, or on behalf of, a Party after the Option Exercise Date for such Collaboration Program that are specifically identifiable or reasonably allocable to:

**1.6.1** the Commercialization of Optioned Products within such Collaboration Program in the Territory in a manner consistent with the applicable Commercialization Plan and in accordance with associated Commercialization Budget, including to the extent consistent with the applicable Commercialization Plan and in accordance with associated Commercialization Budget: sales, pricing, activities relating to obtaining and managing reimbursement from payers and reimbursement authorities, contracting, launch timing, distribution (including order handling, transportation and storage), activities directed to advertising and marketing (including marketing messaging, product positioning, development and distribution of selling, advertising

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and promotional materials), sales tracking and auditing, market research, marketing studies and product usage surveys, provision of medical affairs support staff and conduct of activities by such medical affairs support staff, and scientific and medical advisory boards (including any global medical conferences and other seminars and conventions), peer-to-peer activities and speakers programs;

**1.6.2** the sales force costs for Optioned Products within such Collaboration Program incurred in a manner consistent with such Commercialization Plan and in accordance with associated Commercialization Budget and calculated in accordance with Section 6.4.5;

**1.6.3** the training, operation and management of sales representatives and medical affairs support staff in a manner consistent with the applicable Commercialization Plan and in accordance with associated Commercialization Budget;

**1.6.4** activities pertaining to preparation for and the conduct of Phase IV Studies of Optioned Products within such Collaboration Program in a manner consistent with the applicable Commercialization Plan and in accordance with associated Commercialization Budget;

**1.6.5** the preparation of Regulatory Documentation as reasonably necessary to conduct Commercialization activities for Optioned Products within such Collaboration Program, including any Regulatory Documentation pertaining to pricing and reimbursement approvals for such Optioned Products and any filing fees incurred in connection therewith, all in a manner consistent with the applicable Commercialization Plan and in accordance with associated Commercialization Budget;

**1.6.6** any product liability claims for Optioned Products within the applicable Collaboration Program;

**1.6.7** any recalls and withdrawals of such Optioned Products to the extent treated as an Allowable Expense pursuant to Section 6.10;

**1.6.8** payment made by (i) Denali to a Third Party under an In-License Agreement or (ii) a Party to a Third Party in order to obtain a license or right under a Patent or other intellectual property owned or controlled by such Third Party, in each case, to the extent such payments will be shared by the Parties as Allowable Expenses in accordance with Sections 7.5.1 or 7.5.2;

**1.6.9** the defense, enforcement and cooperation activities (including any freedom to operate analysis, intellectual property clearance or similar activities) incurred in connection with the Optioned Products and to be shared by the Parties to the extent provided in Sections 9.3, 9.4, and 9.5;

**1.6.10** Indemnified Losses and other Out-of-Pocket Costs incurred in connection with Third Party Claims described in Section 13.3 solely to the extent such Indemnified Losses and other Out-of-Pocket Costs are specified in Section 13.3 as to be included in Allowable Expenses;

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**1.6.11** Prosecution and Maintenance of Patents pertaining to such Collaboration Program to the extent provided in Section 9.2 and of trademarks to the extent provided in Section 9.6;

**1.6.12** the Manufacturing Costs for any samples of the Optioned Products within such Collaboration Program, for any Commercial supply of such Optioned Product for sale and for use in any Phase IV Study, all conducted and incurred in a manner consistent with the applicable Commercialization Plan and in accordance with associated Commercialization Budget;

**1.6.13** the Manufacturing related activities pertaining to such Optioned Products not otherwise included in Manufacturing Costs, including stability testing and other CMC support costs for such Optioned Products, but only to the extent such costs are not included in Development Costs and all conducted and incurred in a manner consistent with the applicable Commercialization Plan and in accordance with associated Commercialization Budget; and

**1.6.14** any other FTE Costs and Out-of-Pocket Costs agreed to be shared by the Parties as set forth in this Agreement that are not otherwise covered as a Development Cost.

For clarity, Allowable Expenses are exclusive of and do not include Development Costs.

**1.7** “**Alzheimer’s Disease**” means an Indication [\*\*\*]

**1.8** “**Annual Net Sales**” means the total Net Sales throughout the Territory of a particular Optioned Product in a given Calendar Year.

**1.9** “**Antibody**” means an immunoglobulin (Ig) molecule or fragment thereof that includes (a) a [\*\*\*] and (b) an [\*\*\*].

**1.10** “**Applicable Law**” means federal, state, local, national and supra-national laws, statutes, rules, and regulations, including any rules, regulations, regulatory guidelines, or other requirements of the Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity or country or other jurisdiction hereunder.

**1.11** “**Aspect**” means, with respect to any molecule, the structure or functionality thereof.

**1.12** “**ATV Platform**” means the proprietary platform technology owned or in-licensed by Denali [\*\*\*].

**1.13** “**ATV Platform Claim**” means a Patent claim that (a) Covers the [\*\*\*] or (b) is deemed to be an ATV Platform Claim pursuant to Section 9.1.1.

**1.14** “**ATV Platform Know-How**” means any Information [\*\*\*].

**1.15** “**ATV Platform Patent**” means [\*\*\*].

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**1.16 “ATV Platform Technology”** means ATV Platform Know-How and ATV Platform Patents.

**1.17 “Biologic”** means an Antibody or Non-Antibody Protein.

**1.18 “Biosimilar Competition Percentage”** means, with respect to each Optioned Product in a given country in the Territory in a given Calendar Quarter, the total number of units of all Biosimilar Products sold by one or more Third Parties divided by the sum of: (a) the total number of units of the applicable Optioned Product sold by Takeda, its Affiliates and Sublicensees, and (b) the total number of units of all Biosimilar Products sold by one or more Third Parties, where, in each case, the number of units of the Optioned Product and each Biosimilar Product sold in the relevant country and Calendar Quarter shall be as reported by IMS America Ltd. or any successor thereto and normalized to equivalent units (“IMS”) (or based on equivalent data reported by any other independent sales auditing firm mutually agreed upon by the Parties if IMS data is not available).

**1.19 “Biosimilar Product”** means, with respect to a particular Optioned Product and a particular country, a biologic therapeutic that (a) containing [\*\*\*]; or (b) is otherwise determined by the FDA or other Regulatory Authority outside of the United States to be [\*\*\*] with such Optioned Product, as set forth in 42 U.S.C. 262(k) or other analogous Applicable Law outside the United States. An Optioned Product licensed, marketed, sold, manufactured or produced by Takeda, its Affiliates or Sublicensees shall not constitute a Biosimilar Product.

**1.20 “Business Day”** means a day, other than a Saturday or Sunday, on which banking institutions in San Francisco, California, U.S.A. or Tokyo, Japan are open for business.

**1.21 “Calendar Quarter”** means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

**1.22 “Calendar Year”** means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

**1.23 “Centralized Approval Procedure”** means the procedure through which an MAA filed with the EMA results in a single marketing authorization valid throughout the European Union (or at least all continental Major European Countries that are within the European Union).

**1.24 “Change in Control,”** with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Execution Date:

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**1.24.1** any “person” or “group” (as such terms are defined below) (a) becomes the “beneficial owner” (as defined below), directly or indirectly, of shares of voting capital stock (or similar interests (for instance partnership interests) if a Party is not a corporation) (“Voting Stock”) of such Party representing a majority of the total voting power of all outstanding classes of Voting Stock of such Party or (b) acquires the power, directly or indirectly, to elect a majority of the members of the Party’s board of directors (or similar governing body if a Party is not a corporation); or

**1.24.2** such Party enters into a merger, consolidation or similar transaction with a Third Party (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person or the parent entity of the surviving Person; or

**1.24.3** such Party sells or transfers to any Third Party, in one (1) or more related transactions, properties or assets representing all or substantially all of such Party’s consolidated total assets; or

**1.24.4** the holders of capital stock of such Party approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this definition of Change in Control, (a) “person” and “group” have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term “group” includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act; (b) a “beneficial owner” shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (c) the terms “beneficially owned” and “beneficially own” shall have meanings correlative to that of “beneficial owner.” Notwithstanding the foregoing, a bona fide financing transaction (including any public offering of a Party’s capital stock) shall not be deemed a Change in Control.

**1.25 “Clinical Data”** means the original source patient data and case report forms (CRFs) collected or generated with respect to Clinical Studies of any Optioned Biologic or Optioned Product, together with all analysis, reports, and results with respect thereto.

**1.26 “Clinical Studies”** means any Phase I Trial, Phase II Trial, Phase III Trial, Phase IV Study or any such other test or study in human subjects that is performed pursuant to a Development Plan, Commercialization Plan or an Additional Development Proposal.

**1.27 “CNS Field”** means [\*\*\*].

**1.28 “Co-Commercialization Plan”** means, for each applicable Collaboration Program, a detailed plan and detailed budget for the Commercialization in the Field in the United States and/or China, as applicable, of Optioned Products included in such Collaboration Program for which the Non-Commercial Lead has exercised the co-commercialization option under

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Section 6.2.4, which shall include for each of the United States and China, as applicable: (a) [\*\*\*]; (b) [\*\*\*]; (c) the allocation of Commercialization activities between the Parties to be undertaken with respect to the Optioned Products within such Collaboration Program in the applicable country, including the allocation of responsibility for the [\*\*\*]; (d) an estimated annual sales forecast in each of the United States and China; and (e) the corresponding Commercialization Budget.

**1.29 “Co-Commercialization Territory”** means the United States and China.

**1.30 “Collaboration Program”** means, with respect to an Optioned Target, all Optioned Biologics and Optioned Products Directed to such Optioned Target, and the Development activities, Manufacturing activities and Commercialization activities with respect to such Optioned Biologics and Optioned Products.

**1.31 “Collaboration Program Annual Net Sales”** means the total Net Sales throughout the Territory of all Optioned Products included in a particular Collaboration Program in a given Calendar Year.

**1.32 “Combination Product”** means an Optioned Product that is comprised of or contains one (1) or more Optioned Biologics as an active ingredient together with one (1) or more Other Active Ingredients, whether in the same or different formulations, so long as both the Optioned Biologic(s) and Other Active Ingredient(s) are sold as a single unit or for a single price.

**1.33 “Commercial Lead”** means the Party specified as the “Commercial Lead” pursuant to the terms of Section 6.2.3.

**1.34 “Commercialization”** means any and all activities directed to the preparation for sale of, offering for sale of, or sale of an Optioned Product in each case, as performed in a manner consistent with the applicable Commercialization Plan, including activities related to conducting Phase IV Studies, marketing, promoting, distributing, medical affairs, obtaining pricing and reimbursement approval for an Optioned Product, Manufacturing Optioned Products for commercial sale, samples and Phase IV Studies, importing and exporting such Optioned Product, and the preparation and submission of Regulatory Documentation and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, “**Commercialize**” and “**Commercializing**” means to engage in Commercialization, and “**Commercialized**” has a corresponding meaning. When used as an adjective, “**Commercial**” modifies the following noun to allow for the foregoing activities.

**1.35 “Commercialization Budget”** means a rolling [\*\*\*] Calendar Year budget setting forth the budgeted amounts estimated to be incurred in performance of the related Commercialization Plan in the first Calendar Year (or part thereof) of such budget and the overall estimated budget to be incurred in performance of the related Commercialization Plan next [\*\*\*] successive Calendar Years thereafter. For each Collaboration Program for which Denali has not exercised the Denali Worldwide Royalty Option, each such Commercialization Budget shall include a reasonably detailed budget for FTE Costs and Out-of-Pocket Costs, broken down by Calendar Quarter for the first Calendar Year (or part thereof) and a then current estimate of such FTE Costs and Out-of-Pocket Costs for the next [\*\*\*] successive Calendar

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Years. For each Collaboration Program for which Denali has not exercised the Denali Worldwide Royalty Option, the Global Commercialization Plan shall also include a breakout of costs by functional area or category as determined by the JPT. For each Collaboration Program for which Denali has not exercised the Denali Worldwide Royalty Option and for each country for which the Non-Commercial Lead has exercised the co-commercialization option under Section 6.2.4, each Co-Commercialization Plan shall also include a breakout of costs by functional area or category as determined by the JPT.

**1.36 “Commercialization Plans”** means, collectively, (a) for each Collaboration Program for which Denali has not exercised the Denali Worldwide Royalty Option, the Co-Commercialization Plan, Exclusive Market Commercialization Plan, and Global Commercialization Plan, and (b) for each Collaboration Program for which Denali has exercised the Denali Worldwide Royalty Option, the Global Commercialization Plan, in each case including the corresponding budgets for each such plan.

**1.37 “Commercially Reasonable Efforts”** means, with respect to the efforts to be expended by a Party in connection with a particular activity or objective to be conducted under this Agreement, that level of efforts that [\*\*\*] would normally use, in the exercise of its prudent scientific and business judgment, for the development and commercialization of a bio-pharmaceutical product that it is actively developing or commercializing for a similar patient population at a similar stage of its development or commercialization, taking into account all [\*\*\*] factors that such Party would reasonably take into account, including [\*\*\*], but not taking into account [\*\*\*].

**1.38 “Confidential Information”** means any Information or data provided orally, visually, in writing or other form by or on behalf of one (1) Party (or an Affiliate or representative of such Party or such Party’s Affiliate) to the other Party (or to an Affiliate or representative of such Party or such Party’s Affiliate) in connection with this Agreement, whether prior to, on, or after the Execution Date, including Information pertaining to the terms of this Agreement, a Research Biologic, Optioned Biologic or any Optioned Product (including the Regulatory Documentation and Regulatory Data), any Exploitation of an Optioned Biologic or Optioned Product, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including Takeda Know-How and Denali Know-How), or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, Joint Program Know-How and all Regulatory Documentation generated after the Execution Date and owned by a Party pursuant to this Agreement shall be deemed to be the Confidential Information of both Parties, and the restrictions on use and disclosure in Sections 11.1 and 11.2 shall be deemed to apply to each Party as a receiving Party, regardless of which Party initially generated or disclosed the relevant Joint Program Know-How or Regulatory Documentation, as applicable, to the other Party in connection with this Agreement.

**1.39 “Consent Matter”** means:

**1.39.1** [\*\*\*] and

**1.39.16** any other matter that is explicitly identified as a Consent Matter in this Agreement.

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**1.40 “Control” or “Controlled”** means, with respect to any item of Information, Regulatory Documentation, material, Patent, or other property right, the possession of the right, whether directly or indirectly, and whether by ownership, license, covenant not to sue or otherwise (other than by operation of the license and other grants in Sections 7.1 and 7.2), to grant access to or a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent, or other property right as provided in this Agreement, without violating the terms of any agreement or other arrangement with any Third Party.

**1.41 “Controlling Party”** means the Party specified as the “Controlling Party” in Section 9.2.1.

**1.42 “Corporate Names”** means the Trademarks and logos identified on Schedule 1.42 and such other names and logos, in each case as Denali or Takeda may designate in writing from time to time.

**1.43 “Cover” “Cover”, “Covering” or “Covered”** means, with respect to a product, technology, process or method, that, in the absence of ownership of or a license granted under a Valid Claim, the practice or Exploitation of such product, technology, process or method would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).

**1.44 “Data Package”** means, with respect to a Designated Target and the applicable Research Biologics Directed to such Designated Target, [\*\*\*] set forth in Schedule 1.44 or that are otherwise set forth in the applicable Research Plan or approved by the JSC in accordance with Section 2.3.6 (which, for clarity, shall be a Consent Matter and not subject to either Party’s final decision making authority), which shall include:

**1.44.1** for the then-lead Research Biologics Directed to such Designated Target, [\*\*\*]; and

**1.44.2** other [\*\*\*] from the activities conducted under the applicable Research Plan for such Designated Target with respect any other (a) Antibody that is a Research Biologic Directed to such Designated Target and for which [\*\*\*] and/or (b) Non-Antibody Protein that is a Research Biologic Directed to such Designated Target and for which [\*\*\*].

**1.45 “Denali Business Partner”** means any Third Party to which, as of the Execution Date or during the Term, [\*\*\*].

**1.46 “Denali Know-How”** means Information, including any related Regulatory Documentation and Clinical Data, Controlled by Denali or any of its Affiliates during the Term that is reasonably necessary or actually used to Exploit a Biologic or a Product, in each case, Directed to one (1) or more Designated Target(s), in the Field in the Territory.

**1.47 “Denali Patents”** means Patents Controlled by Denali or any of its Affiliates during the Term that: (i) claim the composition of matter of, or the method of making or using, a Biologic or a Product, in each case, Directed to one (1) or more Designated Target(s); or (ii) are otherwise reasonably necessary or actually used to Exploit a Biologic or a Product, in each case, Directed to one (1) or more Designated Target(s), in the Field in the Territory.

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**1.48 “Denali Technology”** means, collectively, the Denali Patents and the Denali Know-How.

**1.49 “Designated Target”** means any Target specified in Schedule 1.49, or otherwise selected by the Parties during the Term in accordance with the procedures set out in Section 3.1.3 and with respect to which the Parties intend to develop Biologics and Products and to potentially commercialize Products pursuant to this Agreement.

**1.50 “Detail”** means a face-to-face meeting, between a sales representative of the applicable Party, and a health care professional, during which a presentation of the Optioned Product’s attributes is presented in a manner consistent with Applicable Law and industry standards and with the quality of similar presentations made by a Party’s sales representatives for such Party’s other products, if applicable. A Detail does not include a sample drop made by a sales representative. The Parties may agree in the Commercialization Plan to include real-time, electronic Detailing by means of information technology (e.g., Skype).

**1.51 “Development”** means any and all activities related to research, pre-clinical, other non-clinical testing and Clinical Studies (other than Phase IV Studies), including test method development and stability testing, toxicology, formulation, process development, Manufacturing in support of the foregoing activities and manufacturing scale-up, qualification and validation, quality assurance/quality control, any statistical analysis and report writing, the preparation and submission of Regulatory Documentation pertaining to seeking and obtaining Regulatory Approval for a therapeutic product (excluding any activities required solely for obtaining pricing and reimbursement approval but not for other elements of the Regulatory Approval) and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, **“Develop”** means to engage in Development and **“Developed”** has a corresponding meaning.

**1.52 “Development Costs”** means, with respect to a particular Collaboration Program for which Denali has not exercised the Denali Worldwide Royalty Option:

**1.52.1** all Out-of-Pocket Costs and FTE Costs incurred by or on behalf of a Party in a manner consistent with the applicable Development Plan and in accordance with associated Development Budget that are specifically identifiable or reasonably allocable to Development of the applicable Collaboration Program in the Territory. Subject to the foregoing, Development Costs shall include such Out-of-Pocket Costs and FTE Costs incurred in connection with the following activities for the relevant Collaboration Program, as applicable, to the extent performed under and in a manner consistent with the applicable Development Plan and in accordance with the associated Development Budget:

(a) pre-clinical and non-clinical activities such as toxicology and formulation development, test method development, stability testing, quality assurance, quality control development, and statistical analysis;

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(b) Clinical Studies for an Optioned Biologic or Optioned Product within such Collaboration Program, including (i) the preparation for and conduct of such Clinical Studies; (ii) data collection and analysis and report writing; (iii) clinical laboratory work; (iv) regulatory activities in direct connection with such studies, including adverse event recordation and reporting; and (v) advisory meetings in connection with such an Optioned Biologic or Optioned Product;

(c) the preparation of Regulatory Documentation as reasonably necessary to conduct Development activities in a manner consistent with then-current Development Plan and in accordance with the associated Development Budget, including any Regulatory Documentation reasonably necessary to obtain or maintain any Regulatory Approval for an Optioned Product within such Collaboration Program and, in all cases, any filing fees incurred in connection therewith, but excluding any Regulatory Documentation pertaining to pricing and reimbursement approvals and any filing fees associated therewith;

(d) the Manufacturing Costs for any Optioned Biologic, Optioned Product, comparators or placebo reasonably necessary to conduct Development activities in a manner consistent with the then-current Development Plan and in accordance with the associated Development Budget;

(e) the disposal of Biologics, Products and other supplies used in the conduct of Development activities in a manner consistent with the then-current Development Plan and in accordance with the associated Development Budget;

(f) the development of the manufacturing process for an Optioned Biologic or Optioned Product included in such Collaboration Program, manufacturing process validation, including validation batches, and qualification and validation of manufacturing Third Party Providers; and

(g) Indemnified Losses and other Out-of-Pocket Costs incurred in connection with Third Party Claims described in Section 13.3 solely to the extent such Indemnified Losses and other Out-of-Pocket Costs are specified in Section 13.3 as to be included in Development Costs;

**1.52.2** All FTE Costs and Out-of-Pocket Costs incurred by either Party prior to the Option Exercise Date for such Collaboration Program to the extent such activities: [\*\*\*] (such activities, the “**Pre Opt-In Development Activities**”), including such corresponding payments to clinical trial sites and clinical research organizations, Manufacturing Costs for an Optioned Product or Optioned Biologic intended for use in such Clinical Studies, manufacturing process development activities and qualification and validation of Third Party Providers for such Manufacturing activities; and

**1.52.3** any other FTE Costs and Out-of-Pocket Costs agreed to be shared by the Parties as a Development Cost as expressly set forth in this Agreement.

Except as set forth in Section 1.52.2 and Section 1.52.3, Development Costs shall only include those costs incurred by or on behalf of a Party for those activities performed after the Option Exercise Date. For clarity, Development Costs are exclusive of and do not include Allowable Expenses.

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**1.53 “Development Lead”** means the Party specified as the “Development Lead” pursuant to the terms of Section 4.2.3.

**1.54 “Development Plan”** means, on a Collaboration Program-by-Collaboration Program basis, the plan for the Development of Optioned Biologics and Optioned Products under such Collaboration Program, which plan shall include (a) the activities within the Early Stage Development Activities and Late Stage Development Activities to be conducted by each Party to obtain Regulatory Approval for [\*\*\*]; and (b) budgeted amounts estimated to be incurred for conducting activities to be undertaken in a manner consistent with the Development Plan (the “**Development Budget**”); and (c) the number of FTEs of each Party or its Affiliates to be allocated to the relevant Development activities. Each Development Plan and Development Budget shall be reasonably detailed with respect to the Development and Manufacturing activities and estimated FTE Costs and Out-of-Pocket Costs, broken down by Calendar Quarter for the first Calendar Year (or part thereof) and by Calendar Year for the next [\*\*\*] successive Calendar Years.

**1.55 “Directed”** means (a) in the context of a protein-based therapeutic, including an antibody or portion thereof, and a Target that is a Binding Target, that the primary intended mechanism of action of such protein-based therapeutic is to [\*\*\*] such Target or (b) in the context of a protein-based therapeutic, including a non-antibody protein or portion thereof, and a Target that is a Function Target, that the primary intended mechanism of action of such protein-based therapeutic is to [\*\*\*] such Target.

**1.56 “Divestiture”** means (a) the divestiture of a Competing Product through (i) an outright sale or assignment of all material rights in such Competing Product to a Third Party or (ii) an exclusive out-license of all development and commercialization rights with respect to such Competing Product, in each case in the Field with no further material role, influence or authority of the applicable Party, directly or indirectly, with respect to such Competing Product in the Field or (b) the complete cessation of all development and commercialization activities with respect to such Competing Product in the Field. For clarity, the right of the applicable Party to receive royalties, milestones or other payments in connection with an acquiror, assignee or licensee’s development or commercialization of a Competing Product pursuant to sub-section (a) above, shall be permitted for any such Divestiture. When used as a verb, “**Divest**” and “**Divested**” means to cause a Divestiture.

**1.57 “Dollars” or “\$”** means United States Dollars.

**1.58 “Drug Approval Application”** means a Biologics License Application as defined in the FDCA, or any corresponding application for regulatory approval in the Territory, including, with respect to the European Union, a Marketing Authorization Application (a “**MAA**”) filed with the EMA pursuant to the Centralized Approval Procedure or an MAA filed with the PMDA, including, in each case, all supplements, amendments, variations, extensions and renewals thereof.

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- 1.59** “**Early Stage Development Activities**” means, with respect to an Optioned Product(s) within a Collaboration Program, [\*\*\*].
- 1.60** “**Effective Date**” means the Business Day following the HSR Clearance Date.
- 1.61** “**EMA**” means the European Medicines Agency and any successor agency(ies) or authority having substantially the same function.
- 1.62** “**Enforcing Party**” means the Party specified as the “Enforcing Party” in Section 9.3.2.
- 1.63** “**European Union**” means the economic, scientific, and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto.
- 1.64** “**Exclusive Market Commercialization Plan**” means the plan for commercializing an Optioned Product in each Major Market in which the Parties are not co-Commercializing such Optioned Product, which plan shall include a description of the material pre-launch, launch, and subsequent material commercialization activities to be undertaken in such Major Markets and a reasonably detailed budget for such activities.
- 1.65** “**Exclusivity Period**” means, with respect to each Designated Target, the time period: (i) beginning on: [\*\*\*] and (ii) ending on the earlier of the termination or expiration of this Agreement with respect to such Designated Target or [\*\*\*] after the first Regulatory Approval of an Optioned Product Directed to such Designated Target in the United States or a Major European Country, whichever such Regulatory Approval occurs first.
- 1.66** “**Existing Regulatory Documentation**” means the Regulatory Documentation Controlled by Denali or any of its Affiliates as of the Execution Date.
- 1.67** “**Exploit**”, “**Exploitation**”, or “**Exploiting**” means to make, have made, import, export, use, have used, sell, have sold, or offer for sale, including to Develop, Commercialize, register, modify, enhance, improve, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), or otherwise dispose of. “**Exploited**” has a corresponding meaning.
- 1.68** “**F-Star Agreements**” means those agreements listed on Schedule 1.68 between Denali and F-Star Gamma Limited, F-Star Biotechnology Limited, F-Star Biotechnologische Forschungs-Und Entwicklungsges M.B.H. or the shareholders of F-Star Gamma Limited, as applicable, and as may be amended from time to time.
- 1.69** “**FDA**” means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.
- 1.70** “**FFDCA**” means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

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**1.71 “Field”** means the diagnosis, treatment or prevention of any condition, disorder and/or disease in humans.

**1.72 “First Commercial Sale”** means, with respect to an Optioned Product and a country, the first sale for monetary value for use or consumption by the end user of such Optioned Product in such country after Regulatory Approval for such Optioned Product has been obtained in such country and where such sale results in a recordable Net Sale in accordance with the applicable Accounting Standards. Sales prior to receipt of Regulatory Approval for such Optioned Product, such as so-called “treatment IND sales,” “named patient sales,” and “compassionate use sales,” in each case to the extent such Optioned Product is sold at or below cost, shall not be construed as a First Commercial Sale.

**1.73 “FTE”** means the equivalent of the work of one (1) employee full time for one (1) Calendar Year (consisting of at least a total of [\*\*\*] hours per Calendar Year). Each employee utilized by a Party in connection with its performance under this Agreement may be less than or greater than one FTE based on the hours actually worked by such employee performing Development, Commercialization or Manufacturing activities with respect to a Collaboration Program and shall be treated as an FTE on a pro rata basis based upon the actual number of such hours worked divided by [\*\*\*]. For the avoidance of doubt, FTE only applies to employees of a Party, and does not apply to contractors of a Party.

**1.74 “FTE Costs”** means, with respect to a Party for any period, the applicable FTE Rate multiplied by the applicable number of FTEs of such Party performing Development, Commercialization or Manufacturing activities during such period in accordance with the applicable Research Plan, Development Plan, Additional Development Proposal or Commercialization Plan, as the case may be.

**1.75 “FTE Rate”** means, for the period commencing on the Option Exercise Date, the rate agreed upon by the Parties for a particular category of FTE’s activities conducted in the United States. For all other geographic locations outside the United States, the FTE Rate for such locations will be calculated by multiplying the agreed FTE Rate in the United States by a cost of living adjustment between the US and such other geographic location as set forth in [\*\*\*]. The FTE Rate will be increased by a percentage equivalent to the change over the preceding twelve (12)-month period in [\*\*\*].

**1.76 “Global Commercialization Plan”** means, for each Collaboration Program, a high-level global commercialization plan and high-level estimated budget for the Commercialization of Optioned Products included in such Collaboration Program in the Field in the Territory, which shall include: (a) an outline for the strategy for the Commercial launch of, and subsequent Commercialization of, such Optioned Product in the Territory; (b) a summary of pre-launch Commercialization activities to be taken by the Parties, including procurement of any necessary pricing and governmental reimbursement approvals; (c) general marketing and promotional plans for such Optioned Product; (d) an estimated annual sales forecast; and (e) the corresponding Commercialization Budget.

**1.77 “Good Clinical Practices”, “GCP” or “cGCP”** means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines

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adopted by the International Conference on Harmonization (“**ICH**”), titled “Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance,” (or any successor document) including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time.

**1.78 “Good Laboratory Practices”, “GLP”, or “cGLP”** means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.

**1.79 “Good Manufacturing Practice” or “GMP”** means the then-current good manufacturing practices required by the FDA, as set forth in the FFDCa, as amended, and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable Applicable Law related to the manufacture and testing of pharmaceutical materials in jurisdictions outside the U.S., including the quality guideline promulgated by the ICH designated ICH Q7A, titled “Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients” and the regulations promulgated thereunder, in each case as they may be updated from time to time.

**1.80 “HSR Act”** means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

**1.81 “Humanized”** means: (a) with respect to an Antibody, [\*\*\*] (b) with respect to a Non-Antibody Protein [\*\*\*] and “initiation of activities” to Humanize a Biologic shall be deemed to have occurred (x) with respect to an Antibody [\*\*\*] (y) with respect to a Non-Antibody Protein, [\*\*\*]. “**Humanize**” and “**Humanization**” have corresponding meanings.

**1.82 “In-License Agreement”** means the Product In-License Agreements and the Platform In-License Agreements.

**1.83 “IND”** means an application filed with a Regulatory Authority for authorization to commence Clinical Studies, including (a) an Investigational New Drug Application as defined in the FFDCa or any successor application or procedure filed with the FDA, (b) any equivalent of a United States IND in other countries or regulatory jurisdictions, (e.g., Clinical Trial Application (CTA)) and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

**1.84 “Indication”** means a disease or condition and all of its associated signs, symptoms, stages or progression (including precursor conditions). Notwithstanding the foregoing, [\*\*\*] shall be deemed to be separate “Indications” for the purposes of this Agreement.

**1.85 “Information”** means all knowledge of a technical, scientific, business and other nature, including know-how, technology, methods, processes, practices, formulae, instructions,

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skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, Regulatory Data, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, reagents (*e.g.*, plasmids, proteins, cell lines, assays and compounds) and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic or any other form now known or hereafter developed.

**1.86 “Initiation”** means, with respect to any Clinical Study, the [\*\*\*] in such Clinical Study. **“Initiate”** means to engage in Initiation and **“Initiated”** has a corresponding meaning.

**1.87 “Joint Committee”** means the JSC or a JPT, as applicable.

**1.88 “Late Stage Development Activities”** means, with respect to an Optioned Product(s) within a Collaboration Program, all Development activities that are not Early Stage Development Activities.

**1.89 “Limited Funding Cap”** means [\*\*\*].

**1.90 “Major European Country”** means any of France, Germany, Italy, Spain or the United Kingdom.

**1.91 “Major Markets”** means the United States, Japan, and each Major European Country.

**1.92 “Manufacture”, “Manufacturing”, and “Manufactured”** means all activities related to the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, labeling, shipping, and storage of a Biologic, any Product, or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and Commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control.

**1.93 “Manufacturing Cost”** means the costs that pertain to an Optioned Biologic or Optioned Product within a Collaboration Program in the Territory that is either (i) supplied by a Third Party, or (ii) manufactured directly by a Party or an Affiliate of a Party, determined as follows:

**1.93.1** In the case of clause (i) above, Manufacturing Costs means [\*\*\*].

**1.93.2** In the case of clause (ii) above, Manufacturing Costs means [\*\*\*].

**1.94 “Manufacturing Lead”** means the Party specified as the Manufacturing Lead in [Section 5.2](#).

**1.95 “Net Revenues”** means, for each Collaboration Program with respect to which Denali has not exercised the Denali Worldwide Royalty Option: (a) the total Net Sales of all

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Optioned Products included in the applicable Collaboration Program plus (b) Other Income received in connection with the Optioned Products included in such Collaboration Program, minus (c) the following items, to the extent applicable, and subject to this Section 1.95:

**1.95.1** the standard inventory cost (actual acquisition or manufacture cost) of devices used for dispensing or administering the applicable Optioned Product that are shipped with such Optioned Product and included in the gross invoiced sales prices;

**1.95.2** any import or export duties or their equivalent borne by the relevant Party, Affiliate or Sublicensee and specifically attributable to the applicable Optioned Products; and

**1.95.3** the actual insurance, packaging, shipping and freight costs directly related to the delivery of such Optioned Product and special packaging.

For clarity, a particular deduction may only be accounted for once in the calculation of Net Revenues and any deduction included in the calculation of Net Sales shall not be included in Net Revenues. For the avoidance of doubt, and for all purposes under this Agreement, Net Revenues shall be accounted for in accordance with the applicable Party's standard accounting practices, as practiced in the relevant country in the Territory, but in any event in accordance with the applicable Accounting Standards, as consistently applied by such Party in such country in the Territory.

**1.96** "Net Sales" means, with respect to an Optioned Product for any period, the total amount billed or invoiced on sales of such Optioned Product during such period by a Party, its Affiliates, or Sublicensees in the Territory to Third Parties (including Third Party wholesalers or distributors), in bona fide arm's length transactions, less the following deductions, in each case related specifically to such Optioned Product and actually allowed and taken by such Third Parties and not otherwise recovered by or reimbursed to such Party, its Affiliates, or Sublicensees, to the extent deducted in accordance with the applicable Accounting Standards in calculating the "gross to net" revenue adjustment:

**1.96.1** trade, cash and quantity discounts;

**1.96.2** price reductions or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid to governmental authorities or other payees;

**1.96.3** taxes on sales (such as sales, value added, or use taxes) to the extent added to the sale price and set forth separately as such in the total amount invoiced and [\*\*\*];

**1.96.4** amounts repaid or credited by reason of rejections, defects, return goods allowance, recalls or returns, or because of retroactive price reductions, including rebates or wholesaler charge backs;

**1.96.5** the portion of administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers or Medicare Prescription Drug Plans relating to such Optioned Product;

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1.96.6 any invoiced amounts from a prior period which are not collected and are written off by a Party or its Affiliates, [\*\*\*]; and

1.96.7 freight, insurance, import/export, and other transportation charges to the extent added to the sale price and set forth separately as such in the total amount invoiced, as well as any fees for services provided by wholesalers and warehousing chains related to the distribution of such Optioned Product.

Net Sales shall not include transfers or dispositions without charge or for a price less than Manufacturing Cost for charitable, promotional, pre-clinical, clinical, regulatory, or governmental purposes. Net Sales shall include the amount or fair market value of all other consideration received by a Party, its Affiliates or Sublicensees in respect of the Optioned Product, whether such consideration is in cash, payment in kind, exchange or other form. Net Sales shall not include sales of Optioned Product between or among a Party, its Affiliates, or Sublicensees for resale, but the subsequent resale of such Optioned Product to a Third Party shall be included within the computation of Net Sales. For purposes of determining Net Sales, an Optioned Product shall be deemed to be sold when recorded as a sale in accordance with the applicable Accounting Standards. For clarity, a particular deduction may only be accounted for once in the calculation of Net Sales. For the avoidance of doubt, and for all purposes under this Agreement, Net Sales shall be accounted for in accordance with the applicable Commercial Lead's accounting principles, as practiced in the relevant country in the Territory, but in any event in accordance with the applicable Accounting Standards, as consistently applied by such Party in such country in the Territory.

In the event an Optioned Product is a Combination Product, the Net Sales for such Combination Product shall be calculated as follows:

(x) If a Party, its Affiliate, or Sublicensee separately sells in substantial volumes in such country or other jurisdiction in the same reporting period, (A) a product containing as its sole active ingredient an Optioned Biologic contained in such Combination Product (the "**Mono Product**") and (B) products containing as their sole active ingredients the Other Active Ingredients in such Combination Product ("**Other Product**"), the Net Sales attributable to such Combination Product shall be calculated by [\*\*\*].

(y) If a Party, its Affiliates, and Sublicensees do not separately sell in such country or other jurisdiction as described above [\*\*\*].

1.97 "**Non-Antibody Protein**" means a protein molecule that is not an Antibody or fragment of such protein molecule that includes (a) [\*\*\*] ("**Functional Moiety**") and (b) [\*\*\*].

1.98 "**Non-Commercial Lead**" means the Party that is not the Commercial Lead.

1.99 "**Non-Controlling Party**" means the Party that is not the Controlling Party.

1.100 "**Non-Enforcing Party**" means the Party that is not the Enforcing Party.

1.101 "**Non-Manufacturing Lead**" means the Party that is not the Manufacturing Lead.

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**1.102 “Non-Regulatory Lead”** means the Party that is not the Regulatory Lead.

**1.103 “Option Deadline”** means, with respect to a Designated Target and subject to Section 3.2.3(g), the earlier of (a) [\*\*\*] days following Takeda’s receipt of [\*\*\*], or (b) (i) for each Initial Designated Target, the [\*\*\*] anniversary of the Effective Date or (ii) for any Replacement Designated Target, the [\*\*\*] anniversary of the date that the applicable Proposed Target was deemed, pursuant to Section 3.1.3, a Replacement Designated Target, as applicable.

**1.104 “Optioned Biologic”** means: (a) the lead Research Biologic at the time of the applicable Option Exercise Date that is Directed to a Designated Target(s) Developed under a Research Program for such Designated Target(s), (b) [\*\*\*], (c) if [\*\*\*] and (d) any derivatives or fragments of any Biologic that is an Antibody described in subsections (a), (b), and (c) (if any), so long as [\*\*\*]. Notwithstanding the foregoing, “Optioned Biologic”, with respect to a Designated Target that is [\*\*\*].

**1.105 “Optioned Product”** means any Product which contains an Optioned Biologic.

**1.106 “Optioned Target”** means any Designated Target for which Takeda has exercised the Option.

**1.107 “Other Active Ingredient”** means any standalone active pharmaceutical ingredient, which active pharmaceutical ingredient is not covered by any Denali Patents or Takeda Patents. For purposes of clarity, specifically excluded from “Other Active Ingredients” are (a) delivery technologies that increase delivery or exposure of therapeutic proteins in the brain or provide for tissue or cell targeting, and (b) components or modifications to a Biologic that provide additional pharmacological activity (*e.g.*, addition of components or introduction of mutations that would render it bi-specific or multi-specific) or altered pharmacokinetic qualities (*e.g.*, PEGylation).

**1.108 “Other Income”** means any payment (other than Net Sales) when recognized as income or an offset to an expense in accordance with the applicable Accounting Standards by a Party or its Affiliate from a Third Party that is attributable to an Optioned Biologic or Optioned Product within a particular Collaboration Program, including any such payment received in connection with the grant of a sublicense or other right or activity with respect to an Optioned Biologic or Optioned Product, including the grant of an option to obtain such sublicense or other right with respect to an Optioned Biologic or Optioned Product. For clarity, any portion of such payment that is recognized by a Party as an offset to an expense and recorded as Other Income as part of the quarterly reconciliation and true-up process in accordance with Section 8.6.3, shall not also be recorded as an offset against Development Costs or Allowable Expenses for the purposes of such reconciliation and true-up.

**1.109 “Out-of-Pocket Costs”** means amounts actually paid to Third Party vendors or contractors, for services or materials: (a) provided by such Person directly in the performance of activities under and in a manner consistent with a Development Plan or Commercialization Plan and in accordance with the associated Development Budget or Commercialization Budget, as applicable, or (b) to the extent such services or materials apply directly to an Optioned Biologic, an Optioned Product or a Collaboration Program and for which this Agreement provides that

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such costs are sharable between the Parties as a Development Cost or Allowable Expense. For clarity, out-of-pocket costs do not include payments for internal: salaries or benefits; facilities; utilities; general office or facility supplies; insurance; information technology, capital expenditures or the like.

**1.110 “Parkinson’s Disease”** means an Indication [\*\*\*].

**1.111 “Patents”** means: (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications (*i.e.*, described in clauses (a) and (b) above), including utility models, petty patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications (*i.e.*, described clauses (a), (b), and (c) above); and (e) any similar rights, including so-called pipeline protection.

**1.112 “Person”** means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

**1.113 “Phase I Trial”** means a human clinical trial of an Optioned Biologic or Optioned Product, the principal purpose of which is a preliminary determination of safety, tolerability and/or pharmacokinetics in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, including the trials referred to in 21 C.F.R. §312.21(a), as amended. Phase I Trial shall include [\*\*\*].

**1.114 “Phase II Trial”** means a human clinical trial of an Optioned Biologic or Optioned Product, the principal purpose of which is to explore efficacy, Target engagement, pharmacodynamics and/or biological activity in one (1) or more specified doses in the target patient population, or a similar clinical study recommended by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. §312.21(b), as amended. For the purpose of Section 8.3.1, a Phase II Trial shall be [\*\*\*].

**1.115 “Phase III Trial”** means a human clinical trial of an Optioned Biologic or Optioned Product on a sufficient number of subjects in an indicated patient population that is designed to establish that an Optioned Biologic or Optioned Product is safe and efficacious for its intended use and to determine the benefit/risk relationship, warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support a Drug Approval Application for such Optioned Biologic or Optioned Product, including all tests and studies that are required by the applicable Regulatory Authority from time to time, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. §312.21(c), as amended.

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**1.116 “Phase IV Study”** means: (a) a post-approval clinical study for an Optioned Product with respect to any Indication for which Regulatory Approval has been received or that is required or agreed to be conducted as a condition of receiving Regulatory Approval in a country; as well as (b) any marketing study, epidemiological study, modeling and pharmacoeconomic study, investigator-initiated clinical trial or post-marketing surveillance study of an Optioned Product, in each case (for this clause (b)) that is not intended for use as a basis for obtaining Regulatory Approval (including expanded labeling) with respect to such Optioned Product.

**1.117 “PHSA”** means the United States Public Health Service Act, as amended from time to time.

**1.118 “Platform In-License Agreement”** means any agreement between a Party and a Third Party existing as of the Execution Date or entered into during the Term pursuant to which such Party obtains rights to any intellectual property that is [\*\*\*]. Those Platform In-License Agreements as of the Execution Date are listed on Schedule 1.118, and include the F-Star Agreements.

**1.119 “PMDA”** means Japan’s Pharmaceuticals and Medical Devices Agency and any successor agency(ies) or authority having substantially the same function.

**1.120 “Post-Grant Proceedings”** means proceedings conducted with respect to a Patent before a patent office or other administrative agency that is not a court of law following the grant or issuance of such Patent and pursuant to which the validity, enforceability or scope of such Patent is challenged by a Third Party, including a post-grant opposition proceeding, *ex parte* re-examination (but only if such re-examination is requested by a Third Party), *inter partes* review and other post-grant review proceedings. An appeal, including to a court of law, from such Post-Grant Proceeding, shall be understood to be encompassed by the term Post-Grant Proceedings.

**1.121 “Product”** means any pharmaceutical product containing a Biologic, including all forms, presentations, strengths, doses and formulations (including any method of delivery).

**1.122 “Product Claim”** means a Patent claim that (a) Covers [\*\*\*].

**1.123 “Product In-License Agreement”** means any agreement between a Party and a Third Party pursuant to which such Party has obtained rights to any Third Party intellectual property which is [\*\*\*], but excluding in all cases any Platform In-License Agreement. Those Product In-License Agreements existing as of the Execution Date are listed in Schedule 1.123.

**1.124 “Product Labeling”** means, with respect to an Optioned Product in a country or other jurisdiction in the Territory, (a) the full prescribing information for such Optioned Product for such country or other jurisdiction, including any required patient information, approved by the applicable Regulatory Authority and (b) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for such Optioned Product in such country or other jurisdiction.

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**1.125 “Product Patent”** means (a) any Denali Patent or Joint Program Patent that includes a Product Claim or (b) any Takeda Patent that includes only Product Claims that are specifically directed to [\*\*\*].

**1.126 “Product Trademarks”** means the product specific Trademark(s) to be used by a Party or its Affiliates or its or their respective Sublicensees for the Development or Commercialization of Optioned Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates, including the Corporate Names of the Parties).

**1.127 “Proposed Target”** means a Target that has been nominated by a Party after the Effective Date for consideration by the Parties to replace a Designated Target in accordance with the procedures in [Section 3.1.3](#).

**1.128 “Prosecution and Maintenance”** (including variations such as “**Prosecute and Maintain**”) means, with respect to a Patent, the preparing, filing, prosecuting and maintenance of such Patent, including paying all maintenance and/or governmental fees to maintain such Patent in force, and requests for patent term extensions and the like with respect to such Patent, together with the conduct of interferences, Post-Grant Proceedings and other similar proceedings with respect to a Patent, but excluding any Post-Grant Proceedings arising in connection with prosecution of any Product Infringement.

**1.129 “Regulatory Approval”** means, with respect to a country or other jurisdiction in the Territory, all approvals (including Drug Approval Applications), licenses, registrations, or authorizations of any Regulatory Authority necessary to Commercialize an Optioned Biologic or Optioned Product in such country or other jurisdiction, including, where applicable, (a) pricing or reimbursement approval in such country or other jurisdiction, (b) pre-and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (c) approval of Product Labeling.

**1.130 “Regulatory Authority”** means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory authority, agency, department, bureau, commission, council, or other entities (*e.g.*, the FDA, EMA and PMDA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement, including the Exploitation of the Optioned Biologic or Optioned Products in the Territory.

**1.131 “Regulatory Documentation”** means all (a) applications (including all INDs and Drug Approval Applications and other Major Regulatory Filings), registrations, licenses, authorizations, and approvals (including Regulatory Approvals) and designations (including designations of a product as an “orphan” drug or its equivalent outside of the United States), (b) correspondence, materials and reports submitted to or received from Regulatory Authorities (including pre-meeting submissions and minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect

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thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files, and (c) Clinical Data and data contained or relied upon in any of the foregoing, in each case (*i.e.*, clauses (a), (b), and (c) above), to the extent pertaining to an Optioned Biologic or Optioned Product.

**1.132 “Regulatory Exclusivity”** means, with respect to any country or jurisdiction, any exclusive marketing rights or data exclusivity protection conferred by an applicable Regulatory Authority or other governmental body in such country or jurisdiction with respect to a biologic or pharmaceutical product, including any regulatory data protection exclusivity and any extensions to such exclusivity rights.

**1.133 “Regulatory Lead”** means the Party specified as the “Regulatory Lead” in Section 4.4.1.

**1.134 “Research Biologic”** means any Biologic Directed to a Designated Target that is Developed by or on behalf of Denali (or, if applicable, Takeda) in the performance of the Research Program for such Designated Target under this Agreement.

**1.135 “Research Milestone Criteria”** means, with respect to each Research Program and a particular Research Milestone Event, the criteria to be satisfied prior to the payment of the milestone payment corresponding to such particular Research Milestone Event, subject to the terms of Section 3.2.3(f).

**1.136 “Research Plan”** means, with respect to a Research Program, an individualized research plan, which will include (a) all key Development, Manufacturing and regulatory activities (if any) to be conducted to advance [\*\*\*] to be ready for [\*\*\*]; (b) target criteria for the advancement of activities with respect to each Designated Target, including the Research Milestone Criteria with respect to each Research Milestone Event; (c) the Information to be included in the Data Package and (d) the allocation of responsibilities between Parties for such activities; and in the case of each such research plan, that has been agreed to by the Parties or approved by the JSC in accordance with Section 2.3.6.

**1.137 “Research Program”** means, with respect to a Designated Target, all Research Biologics Directed to such Designated Target and the Development activities with respect to such Research Biologics under the Research Plan.

**1.138 “Research Term”** means, with respect to a Designated Target, the period: (a) beginning on (i) Effective Date for the Initial Designated Targets or (ii) for a Replacement Designated Target, the date the applicable Proposed Target was deemed a Replacement Designated Target in accordance with Section 3.1.3; and (b) ending on the earlier of (i) Takeda’s exercise of the Option with respect to such Designated Target, or (ii) the Option Deadline with respect to such Designated Target.

**1.139 “Segregate”** means, with respect to a Denali Competing Product or Takeda Competing Product, as applicable, to use Commercially Reasonable Efforts to segregate the Development, Manufacture and Commercialization activities relating to such product, as applicable, in the Field from Development, Manufacture and Commercialization activities with

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respect to Optioned Biologics and Optioned Products under this Agreement, including using Commercially Reasonable Efforts to ensure that: (a) [\*\*\*]; and (b) [\*\*\*]; *provided*, that, in either case of (a) or (b), [\*\*\*].

**1.140 “Small Patient Population Indication”** means an Indication [\*\*\*].

**1.141 “Subcontract Agreement”** means, with respect to a Third Party Provider, a written agreement between a Party and such Third Party Provider.

**1.142 “Sublicensee”** means a Person that is granted (directly or indirectly) a sublicense by a Party or its Affiliate under the grants in Section 7.1 or Section 7.2, as applicable and as provided in Section 7.3 or other rights to Develop and/or Commercialize an Optioned Biologic or Optioned Product.

**1.143 “Takeda Know-How”** means Information Controlled by Takeda during the Term that is necessary or actually used to Exploit a Biologic or a Product, in each case, Directed to a Designated Target, in the Field in the Territory, including any related Regulatory Documentation and Clinical Data.

**1.144 “Takeda Patents”** means Patents Controlled by Takeda during the Term that are necessary or actually used to Exploit a Biologic or a Product, in each case, Directed to a Designated Target, in the Field in the Territory.

**1.145 “Takeda Technology”** means, collectively, the Takeda Patents and the Takeda Know-How.

**1.146 “Target”** means any biological target(s) (a) to which an antibody, protein or other pharmaceutical product binds in order to elicit a therapeutic or other pharmacodynamic response (any such biological target, a “**Binding Target**”) or (b) that is a protein molecule, such as non-antibody protein molecule, the level of which may be modulated, including by supplementation or replacement, to elicit a therapeutic or other pharmacodynamic response (any such biological target, a “**Function Target**”). Notwithstanding the foregoing, [\*\*\*] shall not be a Target for purposes of this Agreement. [\*\*\*].

**1.147 “Tax” or “Taxes”** means any form of tax or taxation, levy, duty, charge, social security charge, contribution or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs, or excise authority, body or official in the Territory.

**1.148 “Terminated Program”** means (a) with respect to the termination of this Agreement for a Collaboration Program, all Optioned Biologics and Optioned Products within such Collaboration Program subject to such termination, (b) upon expiration of the Option Period for a Designated Target for which Takeda does not deliver an Option Exercise Notice on or prior to the applicable Option Deadline, all Research Biologics within such Research Program, and (c) with respect to termination of this Agreement in its entirety, all Research Biologics, Optioned Biologics and Optioned Products for each Collaboration Program.

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1.149 “Territory” means the entire world.

1.150 “TfR” means [\*\*\*].

1.151 “Third Party” means any Person other than Denali, Takeda and their respective Affiliates.

1.152 “Third Party Provider” means a Third Party service provider to which a Party has subcontracted its activities under and in accordance with this Agreement.

1.153 “Trademark” means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

1.154 “Transition Plan” means the plan, approved by the Parties, for the transfer of the Development Lead and Regulatory Lead from one Party to the other Party, which plan will set forth those activities necessary to transition relevant responsibilities related to such Optioned Product or such Collaboration Program, as the case may be, including the transfer of regulatory responsibilities and pharmacovigilance responsibilities.

1.155 “United States” or “U.S.” means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.156 “Valid Claim” means (a) a claim of an issued and unexpired Patent to the extent such claim has not been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final order, from which no further appeal can be or has been taken, and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; or (b) a claim within a patent application to the extent such claim has not been pending for more than [\*\*\*] years from the earliest filing date to which such claim or the applicable patent application is entitled to claim priority and which claim has not been revoked, cancelled, withdrawn, held invalid or abandoned.

1.157 **Additional Definitions.** In addition, each of the following terms shall have the meaning described in the corresponding Section of this Agreement identified below.

<u>Term</u>	<u>Section</u>	<u>Term</u>	<u>Section</u>
Additional Development Activities	4.2.4	Agreement	Preamble
Additional Event Payment	8.3.3	Aggregate Stock Purchase Price	8.1.1
Additional Development Opt-In Notice	4.2.4(e)(i)	Alliance Manager	2.4
Additional Development Proposal	4.2.4(a)	Bankruptcy Code	14.11
Additional Upfront Consideration	8.1.2	Biosimilar Application	9.3.3
Adverse Ruling	14.2	Binding Target	1.146
AEs	10.1	Breaching Party	14.2
		CMO Supply Agreement	5.6.4
		Co-Funding End Date	8.7.1
		Co-Funding Termination	8.7.2
		Commercialization Wind-Down Period	14.8.2

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<u>Term</u>	<u>Section</u>	<u>Term</u>	<u>Section</u>
Competing Product	7.8.1	Mono Product	1.96(x)
Consenting Party	3.1.3(c)	Neutral Expert	Schedule
Covered ATV Platform Technology	9.1.1		16.6.4
Criteria Achievement Notice	3.2.3(f)	Nominating Party	3.1.3(c)
Declining Party	4.2.4(c)	Non-Breaching Party	14.2
Default Notice	14.2	Option	3.2.4(a)
Denali	Preamble	Option Exercise Date	3.2.4(c)(ii)
Denali Indemnitees	13.1	Option Exercise Fee	8.2.2
Denali New Technology	7.5.1(b)	Option Exercise Notice	3.2.4(c)
Denali Worldwide Royalty Option	8.7.1	Option Period	3.2.4(c)
Development Budget	1.54	Other Product	1.96(x)
Development Milestone	8.3.1	Partial Data Package	3.2.3(g)
Development Wind-Down Period	14.8.1	Party / Parties	Preamble
Dispute	16.6	Patent Working Group	9.2.4
DOJ	15.2	Patient Samples	4.7
Excluded Target	3.1.3(a)	Payments	8.9.1
Execution Date	Preamble	Pharmacovigilance Agreement	10.1
Existing In-License Agreements	7.5.1(a)	Phase 2 Update	4.2.4(e)(i)
Existing Patents	12.2.1	Phase 3 Update	4.2.4(e)(ii)
Fabs	1.9	Pre Opt-In Development Activities	1.52.2
Finance Working Group	8.6.5	Pre-Option Expenses	8.6.3
Force Majeure Event	16.1	Product Infringement	9.3.1
FTC	15.2	Promotional Materials	6.5
Function Target	1.146	Proposed Target Nomination Notice	3.1.3(c)
Functional Moiety	1.97	Proposed Target Response Notice	3.1.3(c)
HSR Clearance Date	15.1	Proposing Party	4.2.4(a)
HSR Conditions	15.1	Prosecuted Infringements	9.3.2
ICH	1.77	Regulatory Approval Update	4.2.4(e)(iii)
IMS	1.18	Regulatory Data	4.4.3
Indemnification Claim Notice	13.4	Replacement Designated Target	3.1.2
Indemnified Losses	13.1	Representative Expert	Schedule
Indemnified Party	13.4		16.6.4
Indirect Taxes	8.10	Required Assigned Technology	9.1.1
Initial Designated Target / Initial Designated Targets	3.1.1	Research Milestone	8.2.1(a)
Joint Program Know-How	9.1.1	Royalty Term	8.7.5(c)
Joint Program Patents	9.1.1	Sales Milestone	8.5
JPT	2.2.1	Significant Biopharmaceutical Company	7.3.2
JSC	2.1.1	Stock Purchase Agreement	Recitals
MAA	1.58	Supply and Quality Agreement	5.4
Major Indication	8.3.1	Takeda	Preamble
Major Regulatory Filings	4.4.2(c)	Takeda Indemnitees	13.2
Manufacturing Process	5.6.1	Takeda New Technology	7.5.2
Manufacturing Technology Transfer	5.6.1	Term	14.1
Manufacturing Transfer Plan	5.2	Terminated Biologic	14.7.1(g)
Material Safety Event	14.6	Terminated Product	14.7.1(g)
Minor Indication	8.3.1	Terminated Target	14.7.1(g)
		Third Party Claims	13.1
		Unavailable	3.1.3(e)
		Working Group	2.6

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**ARTICLE 2**  
**COLLABORATION MANAGEMENT**

**2.1 Joint Steering Committee.**

**2.1.1 Formation.** As soon as practical, but no later than [\*\*\*] days after the Effective Date, the Parties shall establish a joint steering committee (the “JSC”), which shall perform the functions set forth in Section 2.1.2, oversee the conduct of the Research Programs as set forth in Section 2.1.3, and, if applicable, oversee the conduct of the Collaboration Programs in the Territory. The JSC shall consist of an equal number of representatives from each of the Parties, unless otherwise agreed by the Parties in writing.

**2.1.2 Specific Responsibilities.** Prior to Takeda’s exercise of the Option for a Collaboration Program, the JSC shall oversee the Development of the Research Biologics under the Research Programs. From and after Takeda’s exercise of the Option for a Collaboration Program (or any subsequent Collaboration Program), the JSC shall oversee the Development and Commercialization of Optioned Biologics and Optioned Products in the Territory. The JSC shall serve as a forum for the coordination of Development and Commercialization activities for Research Biologics, Optioned Biologics, and Optioned Products in the Territory. In particular, the JSC shall:

- (a) [\*\*\*];
- (b) review and approve any Additional Development Proposal in accordance with Section 4.2.4;
- (c) form Working Groups as needed to fulfill the obligations of the JSC under this Agreement, including a Finance Working Group (unless Denali has exercised the Denali Worldwide Royalty Option for all Collaboration Programs) with responsibilities as provided in Section 8.6.5 and a Patent Working Group with responsibility as provided in Section 9.2.4;
- (d) oversee the Working Groups created by the JSC on all significant strategic issues that fall within the purview of each such Working Group;
- (e) except with respect to matters within the responsibility of the Patent Working Group or as otherwise agreed in writing by the Parties, resolve issues presented to the JSC by any Working Group established by such JSC;
- (f) resolve issues presented to the JSC in accordance with this Agreement; and
- (g) perform such other functions as are set forth herein or as the Parties may mutually agree in writing.

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**2.1.3 Research-Specific Responsibilities.** In addition to the responsibilities set forth above, during each Research Program, the JSC shall:

- (a) review and approve the initial Research Plan for each Replacement Designated Target (if any), other than those Research Plans set forth in Schedule 3.2.1;
- (b) serve as a forum for discussing the conduct of activities in connection with such Research Program and the results of such activities;
- (c) for any Research Program, approve a change to Research Milestone Criteria, a change to the categories of data, or a material decrease to the scope of data, in each case that need to be included in any Data Package; and
- (d) determine whether, for a particular Research Program, the applicable Research Milestone Criteria for Research Milestone Event 1 or Research Milestone Event 2 in the table in Section 8.2.1(a) have been satisfied.

## **2.2 Joint Program Teams.**

**2.2.1 Formation.** Unless otherwise agreed by the Parties at the JSC, within [\*\*\*] days after Takeda's receipt of notice from Denali that it has [\*\*\*] (and Denali shall notify Takeda of such [\*\*\*] within [\*\*\*] Business Days), the Parties shall establish a joint program team for each Research Program (each, a "JPT"), which will become the JPT for the corresponding Collaboration Program if Takeda exercises its Option for such Research Program in accordance with Section 3.2.4; provided that the Parties may agree to appoint a single JPT for one (1) or more Collaboration Programs. References in this Agreement to "the JPT" with respect to activities or matters occurring in connection with a particular Collaboration Program shall mean the JPT established by the Parties for such Collaboration Program, as the case may be. The composition of each JPT shall be mutually agreed by the Parties, with the understanding that the number of representatives from each Party on a JPT may vary over time; *provided* that the JPT shall include at least one (1) representative from each Party at all times. For clarity, a representative from a Party may be a member of more than one (1) JPT.

**2.2.2 Specific Responsibilities.** Each JPT shall oversee the Development of a Research Biologic under the applicable Research Plan and the Development Plan and Commercialization of Optioned Biologics and Optioned Products under the applicable Collaboration Program, in each case, in the Territory. In particular, the JPT shall have the responsibilities set forth in this Section 2.2.2:

- (a) General Activities and Pre-Option Exercise Development Activities. Each JPT shall:
  - (i) form Working Groups as needed to fulfill the obligations of such JPT under this Agreement;
  - (ii) review the budget for any activities conducted prior to the Option Exercise Date if the costs incurred in connection with such activities may be included in Development Costs or Allowable Expenses upon Option exercise for such Collaboration Program;

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- Working Group;
- (iii) oversee the Working Groups created by such JPT on all significant strategic issues that fall within the purview of each such Working Group;
  - (iv) resolve issues presented to such JPT for a decision by any Working Group established by such JPT; and
  - (v) perform such other functions as are set forth in this Agreement, or as the Parties may mutually agree in writing.

(b) Development Activities After Option Exercise. With respect to Development activities for a particular Collaboration Program following Takeda's exercise of its Option for such Collaboration Program (unless Denali exercises the Denali Worldwide Royalty Option for such Collaboration Program), the JPT shall:

- Collaboration Program;
- (i) review and finalize, for the JSC's approval, the initial Development Plan and the associated Development Budget for such Collaboration Program;
  - (ii) review and finalize, for the JSC's approval (if applicable), any amendment to the Development Plan and the associated Development Budget for such Collaboration Program;
  - (iii) review and monitor the activities being conducted under the Development Plan and the progress of such activities;
  - (iv) review and discuss the selection of clinical trial sites, clinical research organizations and other key Third Party Providers for Clinical Studies included in the Development Plan;
  - (v) prepare and approve, the Parties' strategies related to:
    - (A) field-based medical education activities by either Party and grant-based medical education programs in each country within the Co-Commercialization Territory; and
    - (B) funding for any investigator-initiated clinical trials for the Territory, including Clinical Studies involving a safety issue or the head-to-head comparison of an Optioned Product with any other pharmaceutical agent; *provided*, that the decision to authorize the undertaking of such Clinical Study is subject to JSC approval;
  - (vi) review and finalize, for the JSC's approval, any Additional Development Proposal pertaining to such Collaboration Program;
- and
- (vii) review and approve the overall strategies for obtaining Regulatory Approvals for Optioned Products included in such Collaboration Program.

(c) Commercialization Activities. With respect to Commercialization activities for a particular Collaboration Program in the Territory (unless Denali exercises the Denali Worldwide Royalty Option for such Collaboration Program), the JPT shall:

(i) discuss, review, and finalize for the JSC's approval each initial Global Commercialization Plan and each Co-Commercialization Plan (if any) for such Collaboration Program (including the associated Commercialization Budget);

(ii) approve the Exclusive Market Commercialization Plan (including the associated Commercialization Budget); *provided* that such approval shall only be withheld to the extent the Exclusive Market Commercialization Plan (if any) (including the associated Commercialization Budget) is inconsistent with the Global Commercialization Plan, the associated Commercialization Budget, or this Agreement;

(iii) discuss, review, and finalize for the JSC's approval (if applicable), any amendments to a Global Commercialization Plan or Co-Commercialization Plan and the associated Commercialization Budgets related thereto;

(iv) review and approve any decision to launch commercial sales of an Optioned Product in a region or country within the Territory; and

(v) discuss, review, and finalize reasonably in advance of the first Regulatory Approval for an Optioned Product, and annually thereafter, a non-binding [\*\*\*] year estimated sales forecast for the Optioned Products within such Collaboration Program;

(vi) monitor the competitive landscape for the Optioned Products in the Territory;

(vii) discuss, review, and finalize the Parties' strategies related to Phase IV Studies;

(viii) discuss pricing of Optioned Products included in such Collaboration Program; and

(ix) establish a process for reviewing and approving (a) Promotional Materials and (b) training materials and programs for sales representatives, in each case (a) and (b), that are intended for use in any country within the Co-Commercialization Territory.

(d) Manufacturing Activities. With respect to Manufacturing activities for a particular Collaboration Program in the Territory following Takeda's exercise of its Option for such Collaboration Program, the JPT shall:

(i) oversee supply of the Optioned Biologics and Optioned Products as reasonably necessary to conduct Development activities in a manner consistent with the Development Plan and the conduct of Commercialization activities in a manner consistent with the Global Commercialization Plan in order to be able meet expected demand (as reflected in such Global Commercialization Plan);

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- (ii) discuss the worldwide manufacturing, licensure, and sourcing strategies in support of the Manufacturing of the Optioned Biologics and Optioned Products;
  - (iii) review Manufacturing Costs of the Optioned Biologics and Optioned Products, including yields, success rates and other relevant production statistics;
  - (iv) review a supply forecast for the Optioned Products prepared by the applicable Commercial Lead;
  - (v) discuss and make recommendations to the Manufacturing Lead regarding results of regulatory inspections related to an Optioned Biologic or Optioned Product and review steps to be taken by either Party to address any deficiencies noted, it being understood that resolution of any such deficiency shall remain in the sole control of the Manufacturing Lead; and
  - (vi) discuss and make recommendations to the Manufacturing Lead regarding changes in manufacturing sites, testing sites, and responsibilities in the supply chain for each Optioned Biologic and Optioned Product, it being understood that decisions regarding selection of which of internal or Third Party manufacturing and testing sites shall be used to Manufacture the Optioned Biologics and Optioned Products shall remain in the sole control of the Manufacturing Lead, subject to the terms of Section 5.2.

### **2.3 General Provisions Applicable to Joint Committees.**

**2.3.1 Meetings and Minutes.** The JSC shall meet at least [\*\*\*], or as otherwise agreed to by the JSC. Upon formation, the JPT shall meet at least [\*\*\*] per Calendar Quarter, or as otherwise agreed to by the JPT. Meetings of the JSC and each JPT may be conducted by telephone, video-conference, or in-person as determined by the JSC or JPT, as applicable. In-person meetings of each Joint Committee, unless otherwise agreed, shall be held at Denali's offices prior to Takeda's exercise of its Option with respect to each Collaboration Program and shall alternate between Denali's offices and Takeda's offices after Takeda exercises its Option with respect to the relevant Collaboration Program. Regularly scheduled meetings of each Joint Committee may be called by either Party on no less than [\*\*\*] Business Days' notice, or such shorter time period as agreed by the members. Each Party shall make all proposals for agenda items for regularly scheduled meetings of a Joint Committee, and shall provide all appropriate information with respect to such proposed items, to the applicable meeting managers at least [\*\*\*] Business Days in advance of the applicable meeting, or such shorter time period as agreed by the Parties. Each Party may also call a special meeting of a Joint Committee to resolve particular matters requested by such Party, on no less than [\*\*\*] days' notice (or such shorter time period as may be appropriate under the circumstances, but in no event less than [\*\*\*] Business Days' notice). In the case of a special meeting of a Joint Committee called by a Party, the proposed agenda items and appropriate information with respect to such proposed items shall be provided to the applicable meeting managers together with the notice calling for such special meeting to the other Party.

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**2.3.2 Chairpersons.** During the Research Programs, the chairperson for the JSC, and any JPT that has been created, shall be appointed by Denali. At the beginning of the first Calendar Year following Takeda's exercise of its Option for a Collaboration Program, the Joint Committees shall each have co-chairpersons. Denali and Takeda shall each select from their representatives a co-chairperson for each of the Joint Committees. Each Party may change any of its designated chairpersons from time to time upon written notice to the other Party. In the event Denali exercises the Denali Worldwide Royalty Option for all Collaboration Programs, the chairperson for the JSC shall be appointed by Takeda.

**2.3.3 Meeting Managers.** Unless otherwise agreed by the Joint Committee, each Joint Committee shall have meeting co-managers, who need not be a voting member of such Joint Committee. The co-managers will coordinate in good faith for an appropriate distribution of responsibilities between them. The meeting co-managers for the Joint Committees, with assistance and guidance from the Alliance Managers (as appropriate), shall be responsible for calling meetings and for preparing and circulating an agenda in advance of each meeting of such Joint Committee. The meeting co-managers shall prepare and circulate, for review and approval of the Parties, minutes of each meeting within [\*\*\*] Business Days after such meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than [\*\*\*] days after such meeting.

**2.3.4 Procedural Rules.** Each Joint Committee shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement; *provided* that such rules shall not be subject to a deciding vote of either Party having final decision-making authority for such committee. At least (1) representative from each Party on each Joint Committee shall have the requisite seniority to make decisions on behalf of the relevant Party with respect to the issues falling within the decision-making authority of the relevant Joint Committee. A quorum of the Joint Committee shall exist whenever there is present at a meeting at least [\*\*\*] representative appointed by each Party with the requisite seniority to make decisions described in the second sentence of this [Section 2.3.4](#). From time to time, each Party may substitute one (1) (or more, if applicable) of its representatives to a particular Joint Committee on written notice to the other Party, *provided* that the criteria in the second sentence of this [Section 2.3.4](#) shall continue to be satisfied. Representatives of the Parties on a Joint Committee may attend a meeting either in person or by telephone, video conference, or similar means in which each participant can hear what is said by, and be heard by, the other participants.

**2.3.5 Meeting Attendance.** Employees of either Party (or a Party's Affiliate) that are not representatives of such Party on a Joint Committee may attend meetings of such Joint Committee; *provided*, that the Party wishing such persons to participate in a meeting has provided reasonable advance notice to the other Party. Non-employees may only attend meetings of a Joint Committee if such non-employee is bound by written obligations of confidentiality and non-disclosure substantially equivalent to those set forth in [Article 11](#) and with the prior written approval of the other Party (such approval not to be unreasonably withheld, delayed or conditioned).

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### 2.3.6 Joint Committee Decision Making.

(a) The decisions of each Joint Committee shall be by unanimous agreement. Each Party shall have a single vote on a matter to be decided by the applicable Joint Committee irrespective of the number of representatives of such Party in attendance at the applicable Joint Committee meeting. Decisions of a Joint Committee may also be made by a written resolution unanimously agreed by the Parties and signed by at least one representative of each Party appointed to the applicable Joint Committee; it being understood that such unanimous written agreement may be provided by email if the Parties so agree.

(b) If a Joint Committee does not reach unanimous agreement on an issue for decision by the Joint Committee within [\*\*\*] Business Days after the meeting at which such issue was first presented for decision by the Joint Committee, despite good faith efforts to do so, then, unless such issue is a Consent Matter or otherwise to be resolved in accordance with Section 2.3.6(c) below: (i) [\*\*\*] shall have final decision making authority with respect to [\*\*\*] respectively, (ii) the [\*\*\*] shall have final decision making authority with respect to [\*\*\*] matters, and (iii) the [\*\*\*] for shall have final decision making authority with respect to [\*\*\*] matters [\*\*\*]. The decision of the applicable Party's representative on a Joint Committee with respect to an issue within such Joint Committee's decision making authority and for which such Party has the deciding vote shall become the decision of the applicable Joint Committee. All Consent Matters must be [\*\*\*]. If the JSC does not reach unanimous agreement on a Consent Matter or any other matter within the decision-making authority of the JSC within [\*\*\*] Business Days after the JSC meeting at which the applicable issue was first presented to the JSC for decision, such issue shall be resolved in accordance with Section 2.3.6(c) and the resolution of such issue in accordance with Section 2.3.6(c) below shall become the decision of the JSC with respect to such issue.

(c) With respect to any Consent Matter on which the JSC does not reach unanimous agreement within [\*\*\*] Business Days after the first meeting of the JSC at which such issue or dispute is considered, or any other matter or dispute to be resolved in accordance with this Section 2.3.6(c), then, either Party may refer the dispute in writing to the senior executive officers of the Parties, who shall confer in good faith on the resolution of the dispute. Any final decision mutually agreed to by the senior executive officers shall be conclusive and binding on the Parties. If the senior executive officers are not able to agree on the resolution of any such dispute within [\*\*\*] days after such issue was first referred to them, then such dispute shall be [\*\*\*].

(d) Disputes arising between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith, and that are outside of the decision-making authority of the Joint Committees and not within a Party's sole decision-making authority shall be resolved pursuant to Section 16.6.

**2.3.7 Limitations on Authority.** Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in a Joint Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. No Joint Committee shall have the power to, and no deciding vote of a Party or decision of the Neutral Expert on a matter referred to such Person, shall, amend, modify, or waive compliance with this Agreement, which may only be amended or modified as provided in Section 16.8 or compliance

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with which may only be waived as provided in Section 16.11. No decision of any Joint Committee (including by a Party in the exercise of its deciding vote in accordance with Section 2.3.6 or a decision of the Neutral Expert on a matter referred to such Person,) shall (a) finally determine any interpretation of this Agreement or the Parties rights or obligations hereunder, or (b) conflict with any terms and conditions of this Agreement, nor be in contravention of Applicable Law in any material respect.

**2.3.8 Discontinuation of Joint Committees.** Each Joint Committee shall continue to exist until the first to occur of: (a) the Parties mutually agreeing to disband the Joint Committee; and (b) Denali providing to Takeda written notice of its intention to disband and no longer participate in such Joint Committee, *provided*, that Denali shall not give such written notice prior to Takeda's exercise of the Option or the expiration of the last-to-expire Option Period. Notwithstanding anything herein to the contrary, once one or more Joint Committees have been disbanded, such disbanded Joint Committee shall be terminated and thereafter (i) any requirement of a Party to provide Information or other materials to such Joint Committee shall be deemed a requirement to provide such Information or other materials to the other Party, and (ii) any matters previously delegated to the Joint Committee shall be resolved by unanimous agreement of the Parties, or, if the Parties do not reach unanimous agreement, in accordance with the decision making provisions of Sections 2.3.6(b)–2.3.6(c).

**2.4 Alliance Manager.** Each Party shall appoint a person(s) who shall be responsible for the overall coordination and facilitation of the communication, interaction, and cooperation between the Parties and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (each, an "Alliance Manager"). Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

**2.5 Denali Worldwide Royalty Option.** Notwithstanding any of the foregoing provision in this Article 2, in the event Denali exercises the Denali Worldwide Royalty Option with respect to any Collaboration Program, the following shall apply with respect to such Collaboration Program from and after the Co-Funding End Date for such Collaboration Program:

**2.5.1** Takeda shall be designated the Development Lead, Regulatory Lead, Manufacturing Lead (subject to Section 5.2), and Commercial Lead with respect to the such Collaboration Program.

**2.5.2** The applicable JPT with respect to such Collaboration Program shall dissolve. On an at least an [\*\*\*] basis thereafter, Takeda shall submit a revised Development Plan and Global Commercialization Plan (if appropriate based on the then-current Development stage of the Optioned Product) to the JSC for review and comment. Without limiting Section 2.5.3, Takeda shall consider any comments from Denali with respect to such Development Plan or Commercialization Plan in good faith. For clarity, such Development Plans and Global Commercialization Plans shall be limited to the Major Markets and shall only include a description of material activities and a corresponding high-level budget for such activities.

**2.5.3** Takeda shall have the right to make decisions with respect to all matters pertaining to such Collaboration Program previously subject to the decision-making authority of the JSC, including all Consent Matters for such Collaboration Program other than those Consent

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Matters described in Sections 1.39.10–1.39.15, which such matters shall be resolved in accordance with Section 2.3.6(c) if the Parties are unable to reach unanimous agreement with respect to any such matter; *provided* that Takeda may only exercise such final decision making authority with respect to such Consent Matters after escalation to the JSC and if such decisions by Takeda are consistent with the terms and conditions of this Agreement.

**2.5.4** The JSC shall no longer meet with respect to such Collaboration Program after the [\*\*\*] anniversary of the First Commercial Sale of an Optioned Product from such Collaboration Program. Thereafter, Takeda shall provide Denali (via the JSC if still in operation with respect to other Collaboration Programs) [\*\*\*] update of all [\*\*\*] activities in the [\*\*\*] that were completed [\*\*\*] and those planned for the [\*\*\*].

**2.6 Working Groups.** From time to time, a Joint Committee may establish and delegate duties to sub-committees or directed teams (each, a “**Working Group**”) to oversee particular projects or activities (for example, joint finance group and/or joint intellectual property group), *provided* that in no event shall a Joint Committee have the right to, and no Joint Committee shall, delegate its respective decision-making authority to any such Working Group. Each such Working Group shall be constituted as the applicable Joint Committee determines and shall establish its own procedures, to the extent that such procedures are not inconsistent with this Agreement; *provided* that each Working Group shall have adequate functional representation from each Party. Members of a Working Group may also be members of a Joint Committee. Working Groups may be established on an ad hoc basis for purposes of a specific project or on such other basis as the applicable Joint Committee may determine. Each Working Group and its activities shall be subject to the oversight, review, and approval of, and shall report to, the Joint Committee that established such Working Group. In no event shall the authority of a Working Group exceed the authority specified for the Joint Committee that established the Working Group pursuant to this Article 2. All decisions of a Working Group shall be made by unanimous agreement. Any disagreement between the representatives of Takeda and Denali on a Working Group shall be referred to the Joint Committee that established the Working Group for resolution in accordance with Section 2.3.6. Employees of either Party (or a Party’s Affiliate) that are not representatives of such Party on a Working Group may attend meetings of such Working Group; *provided*, that the Party wishing such persons to participate in a meeting has provided reasonable advance notice to the other Party. Non-employees may only attend meetings of a Working Group if such non-employee is bound by written obligations of confidentiality and non-disclosure substantially equivalent to those set forth in Article 11 and with the prior written approval of the other Party (such approval not to be unreasonably withheld, delayed or conditioned).

**2.7 Information.** Each Party shall keep the Joint Committees reasonably informed as to its efforts and activities with respect to the Development, Manufacture, and Commercialization of the Research Biologics, Optioned Biologics, and Optioned Products in the Territory, including by providing such Information as the other Party may reasonably request from time to time.

**2.8 Expenses.** Each Party shall be responsible for all travel and related costs and expenses for its representatives and, if applicable, its (or any of its Affiliate’s) other personnel to attend meetings of, and otherwise participate in, a Joint Committee or other Working Group. All other Out-of-Pocket Costs incurred by the Joint Committees or Working Groups in furtherance

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of a meeting, such as expenses associated with off-site meetings, shall be (a) if the meeting is specific to a particular Collaboration Program prior to the first Regulatory Approval of an Optioned Product in such Collaboration Program, a Development Cost for such Collaboration Program, or (b) otherwise, an Allowable Expense; provided that if Denali has exercised the Denali Worldwide Royalty Option for all Collaboration Programs, such Out-of-Pocket Costs will be shared equally by the Parties.

### ARTICLE 3 DESIGNATED TARGETS; RESEARCH ACTIVITIES

#### 3.1 Designated Targets.

**3.1.1 General.** The Parties may select up to three (3) Designated Targets at any given time to be Developed and Commercialized under and in accordance with this Agreement. Schedule 1.49 sets forth the initial three (3) Designated Targets that have been mutually agreed by the Parties as of the Effective Date (each, an “**Initial Designated Target**” and together, the “**Initial Designated Targets**”).

**3.1.2 Replacement Designated Targets.** A Party may propose to replace an Initial Designated Target with another Target in accordance with and subject to the terms of Section 3.1.3 (such replacement Designated Target, a “**Replacement Designated Target**”); *provided* that such proposal is provided in writing to the other Party prior to the earliest to occur of the following events: (a) the [\*\*\*] year anniversary of the Effective Date; (b) the existence of a Biologic Directed to such original Designated Target [\*\*\*]; or (c) initiation of activities under this Agreement to [\*\*\*]. For avoidance of doubt, such replacement shall be allowed no more than [\*\*\*] for each Designated Target without the Parties’ mutual written agreement, and [\*\*\*] pursuant to this Section 3.1.2 without the Parties’ mutual written agreement. Effective on and after the date of selection of a Replacement Designated Target, (i) the previously selected Designated Target shall no longer be, or be deemed to be, a Designated Target for any purposes of this Agreement, (ii) the licenses granted by each Party to the other Party in the Territory pursuant to Section 7.1 and 7.2 shall terminate with respect to such previously selected Designated Target, and (iii) any exclusivity obligations of a Party with respect to such previously selected Designated Target pursuant to Section 7.8 shall terminate.

**3.1.3 Selection and Replacement Procedures.** The following procedure shall apply with respect to the selection of a Replacement Designated Target:

(a) Neither Party may nominate a Proposed Target that is identified on the excluded Target list set forth in Schedule 3.1.3(a) or that is otherwise not applicable to [\*\*\*] (each such Target, an “**Excluded Target**”).

(b) Prior to the nomination of any Proposed Target pursuant to Section 3.1.3(c), the Parties shall discuss any potential Proposed Target at the JSC and the each Party shall consider the other Party’s comments on such Proposed Target in good faith.

(c) To nominate a Proposed Target as a Designated Target, a Party (such Party, the “**Nominating Party**”) shall provide to the other Party (such Party, the

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“**Consenting Party**”) a written description of the Proposed Target specifically referencing this Section 3.1.3(c), including to the extent available, the NCBI Entrez Gene Symbol and NCBI RefSeq accession (each, a “**Proposed Target Nomination Notice**”). Each Proposed Target Nomination Notice shall not include more than [\*\*\*] Proposed Target. Within [\*\*\*] Business Days following the Consenting Party’s receipt of the Proposed Target Nomination Notice with respect to a Proposed Target, the Consenting Party shall notify the Nominating Party in writing of its acceptance or rejection of such Proposed Target as a Replacement Designated Target (each, a “**Proposed Target Response Notice**”), [\*\*\*]. If the Proposed Target Response Notice indicates that the Consenting Party accepts the Proposed Target, Denali shall prepare, for the JSC’s approval, a Research Plan with respect to such Proposed Target. Upon approval by the JSC of such Research Plan, such Proposed Target shall be deemed to be a Replacement Designated Target.

(d) If a Nominating Party provides a Proposed Target Nomination Notice to the Consenting Party, such Nominating Party shall not provide any other Proposed Target Nomination Notice to the Consenting Party until the earlier of receipt of a Proposed Target Response Notice from the Consenting Party or [\*\*\*] Business Days following the Consenting Party’s receipt of the Proposed Target Nominating Notice.

(e) For any of the first [\*\*\*] Proposed Targets that is not Unavailable with respect to the Consenting Party, if the Consenting Party rejects any such Proposed Target under Section 3.1.3(c), then for a period beginning on the date of the applicable Proposed Target Response Notice and ending [\*\*\*] months thereafter, the Consenting Party shall not, [\*\*\*]. For avoidance of doubt, the provisions of this Section 3.1.3(e) shall not limit a Party’s [\*\*\*] Directed to (i) any Target that is Unavailable or (ii) any Target that is not Unavailable other than a Target that was one of the first [\*\*\*] Proposed Targets that were not Unavailable. As used herein, “**Unavailable**” means that, with respect to the applicable Proposed Target and a Consenting Party, (A) such Proposed Target is an Excluded Target or (B) such Consenting Party has: (i) [\*\*\*]; (ii) [\*\*\*], or (iii) [\*\*\*]. Where a Proposed Target comprises more than one Target, such Proposed Target shall be Unavailable if any of such Targets are Unavailable.

(f) For clarity, notwithstanding the provisions of this Section 3.1.3, the Parties could mutually agree to select a Proposed Target that is an Excluded Target or otherwise Unavailable as described in Section 3.1.3(e)(B)(i) or (iii) as a Replacement Designated Target.

## **3.2 Research Plans and Activities.**

**3.2.1 Research Plans.** The initial Research Plans for the Initial Designated Targets are set forth in Schedule 3.2.1. The initial Research Plan for a Designated Target (other than an Initial Designated Target) shall be prepared by Denali as provided in Section 3.1.3(c) and subject to the approval by the JSC in accordance with Section 2.1.3(a) and Section 2.3.6.

**3.2.2 Amendments to a Research Plan.** The JSC shall review the Research Plan for each Research Program on a regular basis, and in no event less frequently than [\*\*\*] Calendar Year, and the progress of activities being conducted for each Research Program against the Research Plan. Either Party may propose amendments to the Research Plan for a given

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Research Program from time to time as appropriate, to take into account completion, commencement or cessation of activities contemplated in the then-current Research Plan for, as well as any newly available Information related to, such Research Program. Such amendments shall be effective upon JSC approval and subject to the decision making in accordance with Section 2.3.6.

### 3.2.3 Research Activities.

(a) **Efforts.** Each Party shall use Commercially Reasonable Efforts to [\*\*\*]. Each Party shall perform any and all of its Development activities with respect to a Research Program in good scientific manner and in compliance with all Applicable Law, including applicable national and international (e.g., ICH, GCP, GLP, and GMP) guidelines.

(b) **Allocation of Activities.** Each Party shall be responsible for day-to-day implementation of the research activities allocated to it under a Research Plan or for which it is otherwise responsible under the applicable Research Program pursuant to this Agreement. Denali shall be the Development Lead for each Research Plan. Takeda shall conduct or otherwise be responsible for activities under any Research Program only upon the mutual agreement of the Parties and to the extent reflected in the then-current Research Plan for such Research Program.

(c) **Research Reports.** For each Research Program, Takeda may designate internal subject matter experts with respect to such Research Program. For clarity, Takeda may designate the same subject matter experts for multiple Research Programs. Denali shall, on at least a [\*\*\*] basis, informally communicate with such designated subject matter experts with respect to the ongoing Development activities for such Research Program. Without limiting the foregoing, at each meeting of the JSC, each Party shall report on the Development activities such Party has performed (or caused to be performed) under the applicable Research Plan since the last meeting of the JSC, and the results of such activities, all in accordance with reporting procedures reasonably determined by the JSC from time to time. The JSC will evaluate the progress of such Development activities and results in relation to the goals of the applicable Research Plan and may request a Party provide such other information as may be reasonably necessary to understand the status of the applicable Research Program and the progress towards achievement of the Research Milestones in such Research Program.

(d) **Research Plan Expenses.** Each Party shall be solely responsible for any Out-of-Pocket Costs or FTE Costs it incurs in furtherance of the activities assigned to it under an applicable Research Plan.

(e) **Regulatory Activities.** Denali shall be the Regulatory Lead for all Research Biologics Directed to a given Designated Target prior to the Option Exercise Date for such Designated Target. Prior to the Option Exercise Date for a particular Designated Target, Denali shall provide Takeda with a reasonable opportunity to review and comment on any material communications with the applicable Regulatory Authorities with respect to Research Biologics included in the Research Program for such Designated Target, including to the extent existing prior to the Option Exercise Date, any INDs and other Major Regulatory Filings. Denali shall consider in good faith any such comments of Takeda with respect to such communications.

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Denali shall also keep Takeda reasonably informed, via the JSC and/or Takeda's designated subject matter experts, regarding any substantive meetings with any Regulatory Authority regarding Research Biologics Directed to a particular Designated Target.

(f) **Achievement of Research Milestone Criteria.** For each Research Program, Denali shall notify Takeda and the JSC if Denali determines in good faith that the Research Milestone Criteria for a particular Research Milestone Event have been satisfied by a Research Biologic within such Research Program (each a "**Criteria Achievement Notice**") and shall provide Takeda and the JSC with [\*\*\*]. If, within [\*\*\*] Business Days after the Criteria Achievement Notice, Takeda does not notify the JSC in writing that it objects to Denali's determination that the applicable Research Milestone Criteria have been satisfied, such Research Milestone Criteria shall be deemed to have been satisfied. If Takeda issues an objection notice pursuant to the preceding sentence within the applicable [\*\*\*]-Business Day period, the matter shall [\*\*\*].

(g) **Data Package Disclosure.** For each Research Program, Denali shall deliver to Takeda the Data Package as soon as reasonably practicable after completion of the activities under the applicable Research Plan if such activities are completed prior to the expiration of the applicable Option Deadline. In the event Denali reasonably believes that [\*\*\*], Denali shall, no later than [\*\*\*] days before the applicable Option Deadline for such Research Program, provide Takeda with [\*\*\*] (the "**Partial Data Package**"). Notwithstanding the foregoing, if at the time the Partial Data Package is delivered to Takeda, there are [\*\*\*], Denali shall [\*\*\*] and the applicable Option Deadline shall be extended by up to [\*\*\*] months, or, if earlier, until [\*\*\*] days after Takeda receives such Information. Along with the delivery of each of the Data Package, or Partial Data Package, as the case may be, Denali shall provide Takeda with [\*\*\*]. To the extent Takeda has incurred or expects to incur, prior to the Option Exercise Date, any FTE Costs or Out-of-Pocket Costs to be included as a Development Cost under Section 1.52.2, Takeda shall provide to Denali details of such FTE Costs and Out-of-Pocket Costs promptly following Denali's disclosure of each of the Data Package, or Partial Data Package, as the case may be. For avoidance of doubt, the reference of the conduct of any specific Development activities under this Section 3.2.3(g) shall not be construed as altering either Party's obligations under Section 3.2.3(a).

#### 3.2.4 Option Grants to Takeda.

(a) **The Option.** Subject to the terms and conditions of this Agreement, Denali hereby grants to Takeda, on a Designated Target-by-Designated Target basis, the exclusive right, but not the obligation, to obtain the licenses set forth in Section 7.1.2 with respect to the Collaboration Program for such Designated Target (each, an "**Option**").

(b) **Review of the Data Package.** Upon Takeda's receipt of the Data Package or Partial Data Package, as applicable, Takeda shall have the remaining Option Period to determine whether it will submit the Option Exercise Notice. During this review period, upon Takeda's reasonable request, Denali shall make reasonable efforts to promptly make available to Takeda: (i) its and its Affiliates' employees and consultants who performed the activities on behalf of Denali under the Research Plan, including the preparation of the Data Package; and (ii) any additional Information or data then-existing and under Denali's possession or control related to the Research Program that is reasonably necessary in evaluating such Data Package or Partial Data Package, including with respect to the then-current development CMC status.

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(c) **Option Exercise Mechanics.** Takeda shall have the right to exercise its Option with respect to a Designated Target by providing written notice of such election to Denali (the “**Option Exercise Notice**”) at any time on or after the Effective Date and prior to the occurrence of the Option Deadline with respect to such Designated Target (the “**Option Period**”). Along with such Option Exercise Notice, Takeda shall specify in writing [\*\*\*]. For the avoidance of doubt, Takeda’s election to exercise its Option for a particular Research Program prior to Denali’s delivery of a Data Package or Partial Data Package pursuant to Section 3.2.3(g) above, shall not otherwise affect the allocation of rights and responsibilities between the Parties under this Agreement with respect to such Research Program.

(i) **Option Exercise.** If Takeda submits the Option Exercise Notice to Denali with respect to a particular Designated Target, Takeda shall pay the Option Exercise Fee in accordance with Section 8.2.2; [\*\*\*]. For clarity, in the event an approval from a governmental authority is required, the Parties shall seek such approval in accordance with Article 15.

(ii) **Option Exercise Date.** The exercise of the Option shall become effective, and the licenses granted under Sections 7.1.2 and 7.2.2 with respect to such Designated Target and the corresponding Collaboration Program shall be in full force and effect, immediately upon Takeda’s payment of the Option Exercise Fee set forth in Section 8.2.2 to Denali (the “**Option Exercise Date**”).

(iii) **Failure to Exercise Option.** If Takeda does not provide Denali with an Option Exercise Notice or if Takeda provides Denali with written notice of its decision not to exercise the Option with respect to a Collaboration Program for a Designated Target prior to the Option Deadline, then from and after the expiration of the Option Period or Denali’s receipt of such notice not to exercise the Option, as applicable, each Party will be free itself or with or through an Affiliate or Third Party, to develop and commercialize any Biologics or Products Directed to such Terminated Target, and the Parties’ respective rights and obligations with respect to such Target under Section 7.8 shall terminate. In such event, the provisions of Sections 14.7 and 14.8 shall apply with respect to the Terminated Program and Takeda shall grant licenses to Denali as provided in Section 14.7.1 (and subject to the procedures described therein), in each case to the extent applicable.

#### ARTICLE 4 DEVELOPMENT AND REGULATORY ACTIVITIES AFTER OPTION EXERCISE

**4.1 General.** Subject to the terms of this Agreement, the JPT and the JSC (as applicable) shall, following Takeda’s exercise of its Option with respect to a particular Designated Target, oversee and coordinate the Development of Optioned Biologics and Optioned Products within the applicable Collaboration Program in the Field in the Territory.

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## 4.2 Development Plan and Activities.

**4.2.1 Development Plan.** Promptly after the formation of the JPT with respect to an applicable Designated Target, the applicable Development Lead shall prepare in consultation with the other Party, for the JPT's review and the JSC's approval, the portion of a Development Plan corresponding to the Development activities for which it is the Development Lead, for the Development of the Optioned Products within the Collaboration Program for such Designated Target. The Development Plan for each Collaboration Program shall reflect Commercially Reasonable Efforts [\*\*\*]. Unless Denali has exercised the Denali Worldwide Royalty Option for a particular Collaboration Program, each Development Plan for a Collaboration Program shall include a role for Denali, as mutually agreed by the Parties. In the event Denali has exercised the Denali Worldwide Royalty Option with respect to a Collaboration Program, the Development Plan for such Collaboration Program shall be limited to [\*\*\*]; provided that the foregoing limitations on specific content of the Development Plan shall not be construed as to limit (or be deemed to limit) Takeda's diligence obligations under this Agreement.

**4.2.2 Amendments and Updates.** The JPT shall review the Development Plan for each Collaboration Program on a regular basis, and in no event less frequently than [\*\*\*] Calendar Year. Either Party, through its representatives on the JPT, may propose amendments to a Development Plan and the associated Development Budget for a given Collaboration Program from time to time. In any event, an updated Development Plan, including the associated Development Budget, for each Collaboration Program shall be provided by the JPT (and approved by the JSC as required) no later than December 1 of each Calendar Year. If such revised Development Plan (and associated Development Budget) is not approved by the JSC, then, until such time as an updated Development Plan for such Collaboration Program is approved by the JSC in accordance with Section 2.3.6: (a) the then-current Development Plan (and associated Development Budget) shall continue to govern the Parties' Development activities under this Agreement with respect to the applicable Collaboration Program; and (b) each Party shall be obligated to conduct Development activities allocated to such Party under such then-current Development Plan and shall be permitted to incur Development Costs consistent with such associated Development Budget, which Development Costs shall be shared by the Parties in accordance with Section 8.6.

### 4.2.3 Development Activities.

(a) **Efforts.** Each Party shall use Commercially Reasonable Efforts to [\*\*\*]. Each Party shall perform any and all of its Development activities with respect to each Collaboration Program in good scientific manner and in compliance with all Applicable Law, including applicable national and international (*e.g.*, ICH, GCP, GLP, and GMP) guidelines, informed consent and institutional review board regulations, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects.

(b) **Allocation of Activities.** Each Party shall be responsible for day-to-day implementation of the Development activities allocated to it under a Development Plan. The Development Lead shall be responsible for preparing clinical trial designs and protocols, sponsoring Clinical Studies, engaging Third Party Providers, and shall be primarily responsible for the conduct of any such Early Stage Development Activities or Late Stage Development Activities, as the case may be, consistent with the then-current Development Plan for such Collaboration Program.

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(c) **Designation of Development Lead.** Unless otherwise agreed by the Parties, for each Collaboration Program, Denali shall be the Development Lead with respect to Early Stage Development Activities and Takeda shall be the Development Lead with respect to Late Stage Development Activities; *provided* that after initiation of Late Stage Development Activities with respect to any Optioned Biologic or Optioned Product for a particular Indication, Takeda shall be the Development Lead with respect to all subsequent Development of such Optioned Biologic or Optioned Product for such Indication, including any Clinical Study that is Initiated thereafter for such Indication, whether Early Stage Development Activities or Late Stage Development Activities. Notwithstanding the initiation of Late Stage Development Activities for a particular Optioned Product within a Collaboration Program for an Indication, unless otherwise agreed, Denali will continue to be Development Lead for [\*\*\*]. In addition to any activities that the Parties agree the Non-Development Lead may conduct, the Non-Development Lead shall have the right to have one (1) or more of its employees attend, and participate in, all global advisory board meetings and other meetings with key opinion leaders regarding each Collaboration Program, or any Optioned Biologics or Optioned Products included in such Collaboration Program. Neither Party shall conduct, directly or indirectly, any Clinical Study or other Development of any Optioned Biologic or Optioned Product within a particular Collaboration Program in the Field in the Territory, except as expressly permitted in this Article 4.

(d) **Transition of Development Lead.** Reasonably in advance of the Initiation of Late Stage Development Activities for each Collaboration Program, the JPT will prepare a Transition Plan to be approved by the Parties for the transfer of the Development Lead with respect to such Optioned Product from Denali to Takeda.

(e) **Development Reports.** For each Collaboration Program, each Party shall report on the Development activities such Party has performed (or caused to be performed) under such Collaboration Program in accordance with the procedures established by the JPT. The JPT shall evaluate the work performed in relation to the goals of the applicable Development Plan. The Parties shall provide such other Information as may be reasonably requested by the JPT with respect to such Development activities.

**4.2.4 Additional Development Activities.** Each Party shall be permitted to undertake Development activities for an Optioned Product within a particular Collaboration Program for [\*\*\*] (such activities, the “**Additional Development Activities**”); *provided* that such Party complies with the provisions of this Section 4.2.4.

(a) **Additional Development Proposals.** If a Party (such Party, the “**Proposing Party**”) desires to undertake Additional Development Activities, such Party shall submit to the JPT a proposal for the addition of such Additional Development Activities to the Development Plan that includes a proposed work plan, timeline and budget for such Additional Development Activities (an “**Additional Development Proposal**”). The Additional Development Proposal shall be prepared in a similar scope and format of a Development Plan. The Proposing Party shall provide the JPT with any additional Information related to the Additional Development Proposal reasonably requested by the JPT.

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(b) **Inclusion of Additional Development Activities in the Development Plan.** The JPT shall review and decide on such Additional Development Proposal within [\*\*\*] days after its receipt of such Additional Development Proposal; *provided* that such time shall be extended if the Proposing Party has not provided all available Information reasonably requested by the JPT. If the JPT approves an Additional Development Proposal, such Additional Development Proposal shall be submitted promptly to the JSC for review. If the JSC approves an Additional Development Proposal, the Development Plan shall be deemed to be amended to include the Additional Development Activities and associated budget upon approval of such Additional Development Proposal by the JSC. For the sake of clarity, all FTE Costs and Out-of-Pocket Costs incurred thereafter by the Parties in performing such Additional Development Activities shall be treated as Development Costs until the Co-Funding End Date after Denali exercises the Denali Worldwide Royalty Option for the applicable Collaboration Program. If the JSC does not approve the Additional Development Proposal, inclusion of the Additional Development Activities within the Development Plan shall not be subject to resolution under Section 2.3.6, and instead the provisions of Sections 4.2.4(c)-(e) shall apply.

(c) **Objection by the Other Party.** If the JPT and JSC do not timely approve an Additional Development Proposal within the time periods set forth in Section 4.2.4(b), the other Party (the “**Declining Party**”) may, within [\*\*\*] Business Days of the JSC’s final vote with respect to the Additional Development Proposal, initiate the dispute resolution arbitration procedures set forth in Section 16.6.4, if, and only if, the Declining Party determines reasonably and in good faith that (i) [\*\*\*] or (ii) [\*\*\*]. Upon initiation of dispute resolution, the Proposing Party will be prohibited from [\*\*\*] until such time that dispute is finally determined in accordance with Section 16.6.4.

(d) **Performance of Additional Development Activities.** If the JPT and JSC do not timely approve an Additional Development Proposal within the time periods set forth in Section 4.2.4(b) and either (i) the Declining Party does not timely initiate the dispute resolution arbitration procedures set forth in Section 16.6.4, or (ii) the dispute is finally determined in accordance with Section 16.6.4 in favor of the Proposing Party, the Proposing Party may, upon notice to the JSC, conduct the relevant Additional Development Activities described in the Additional Development Proposal. For clarity, an Optioned Product that is the subject of Additional Development Activities shall continue to be an Optioned Product for all purposes of this Agreement. The Proposing Party shall be the Development Lead and Regulatory Lead with respect to such Additional Development Activities, including with respect to obtaining any required Regulatory Approval, until the Proposing Party’s receipt of an Additional Development Opt-In Notice for such Additional Development Activities, after which the provisions of Section 4.2.3 shall apply. In the event the Proposing Party is not the Manufacturing Lead for the applicable Optioned Biologic or Optioned Product, if a Party so requests, the Proposing Party and the Manufacturing Lead shall enter into a Supply and Quality Agreement in accordance with Section 5.4. Additional Development Activities undertaken by the Proposing Party shall be subject to the oversight of the JPT for the applicable Collaboration Program; *provided* that the Proposing Party will have final decision making authority with respect to any issue related to the Additional Development Activities. The Proposing Party shall bear all costs

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associated with the Additional Development Activities it undertakes and such costs shall not be taken into account as Development Costs or as Allowable Expenses. Except as expressly set forth in this [Section 4.2.4\(d\)](#), the conduct of the Additional Development Activities will be subject to all terms and conditions of this Agreement relating to Development of Optioned Products. At each meeting of the JPT, the Proposing Party shall report its progress with regard to the Additional Development Activities in the same manner as the Parties provide reports to the JPT with respect to activities covered by the Development Plan for the relevant Collaboration Program, including providing formal written reports of the results related to the Additional Development Activities, as well as the actual costs incurred by the Proposing Party, along with estimated future budgets.

(e) **Opt-In for Additional Development Activities.**

(i) **Completion of a Phase 2 Trial.** Within [\*\*\*] days after the date of the database lock for the first Phase II Trial related to the Additional Development Activities, the Proposing Party shall furnish to the JPT and the Declining Party, a written report of the results of such Clinical Study and the Additional Development Costs incurred by the Proposing Party (the “**Phase 2 Update**”). The Proposing Party shall also provide the JPT with any other Information related to the Additional Development Activities which is reasonably requested by the JPT and available to the Proposing Party. If, within [\*\*\*] days of the Declining Party’s receipt of the Phase 2 Update, it notifies the JPT and the Proposing Party in writing that it desires to include the Additional Development Activities into the Development Plan (an “**Additional Development Opt-In Notice**”): (1) the Declining Party shall, subject the review rights set forth in to [Section 8.6.1\(b\)](#), pay to the Proposing Party an amount equal to [\*\*\*] of the Additional Development Costs identified in the Phase 2 Update and (2) the terms of [Section 4.2.4\(e\)\(iv\)](#) shall apply.

(ii) **Completion of Phase 3 Trial.** In the event that the Declining Party does not submit the Additional Development Opt-In Notice in accordance with [Section 4.2.4\(e\)\(i\)](#), then within [\*\*\*] days after the date of the database lock for the first Phase III Trial related to the Additional Development Activities, the Proposing Party shall furnish to the JPT and the Declining Party, a written report of the results of such Clinical Study and the Additional Development Costs incurred by the Proposing Party (the “**Phase 3 Update**”). The Proposing Party shall also provide the JPT with any other Information related to the Additional Development Activities which is reasonably requested by the JPT and available to the Proposing Party. If, within [\*\*\*] days of the Declining Party’s receipt of the Phase 3 Update, the Declining Party submits an Additional Development Opt-In Notice to the JPT and Proposing Party: (1) the Declining Party shall, subject the review rights set forth in to [Section 8.6.1\(b\)](#), pay to the Proposing Party an amount equal to [\*\*\*] of the Additional Development Costs identified in the Phase 2 Update and Phase 3 Update and (2) the terms of [Section 4.2.4\(e\)\(iv\)](#) shall apply.

(iii) **Regulatory Approval.** In the event that the Declining Party does not submit the Additional Development Opt-In Notice in accordance with [Section 4.2.4\(e\)\(i\)](#) or (ii), and the Proposing Party receives Regulatory Approval in a Major Market country with respect to the Additional Development Activities, the Proposing Party shall promptly notify the Declining Party in writing of such Regulatory Approval and the Additional Development Costs incurred by the Proposing Party (the “**Regulatory Approval Update**”).

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Promptly after receipt of a Regulatory Approval Update, the Declining Party shall be required to submit an Additional Development Opt-In Notice to the JPT and the Declining Party and the Declining Party shall, subject the review rights set forth in to Section 8.6.1(b), pay to the Proposing Party an amount equal to [\*\*\*] of the Additional Development Costs identified in the Phase 2 Update, Phase 3 Update and Regulatory Approval Update and the terms of Section 4.2.4(e)(iv) shall apply; *provided* that such amount shall be reduced to [\*\*\*] of such Additional Development Costs if [\*\*\*].

(iv) **Additional Development Opt-In Notice.** Immediately upon the Proposing Party's receipt of the Additional Development Opt-In Notice: (i) the Additional Development Activities (if any) for such Optioned Product and the applicable Indication of the Additional Development Activities shall be deemed to be included in the Development Plan for the relevant Collaboration Program; (ii) the then-current plan and budget for such Additional Development Activities shall be deemed to be included within and part of the Development Plan, and shall control with respect to such Additional Development Activities unless and until an amendment to the Development Plan providing for a different or modified plan and budget is approved by the JSC in accordance with Section 4.2.2; (iii) all Out-of-Pocket Costs and FTE Costs incurred thereafter in connection with such Additional Development Activities shall be treated as Development Costs and shared by the Parties until the Co-Funding End Date after Denali exercises the Denali Worldwide Royalty Option for the applicable Collaboration Program; and (iv) to the extent one or more Commercialization Plans for such Optioned Product then-exist and the Phase 3 Update or Regulatory Approval Update has occurred, the JPT will update such Commercialization Plans in accordance with Section 6.3.4 to address Commercialization of such Optioned Product for the applicable Indication in any country for which Regulatory Approval is obtained.

(v) **Worldwide Royalty Option.** Notwithstanding the foregoing, in the event Denali exercises the Denali Worldwide Royalty Option with respect to any Collaboration Program, Denali shall not be permitted to undertake any Additional Development Activities pursuant to this Section 4.2.4, and Takeda shall have the right to conduct Additional Development Activities by amending the applicable Development Plan, and this Section 4.2.4 will not apply to such activities by Takeda.

**4.2.5 Development Costs.** Each Party will be solely responsible for all FTE Costs and Out-of-Pocket Costs such Party incurs in connection with the Development of Optioned Biologics and Optioned Products in any Collaboration Program after the Co-Funding End Date following Denali's exercise of the Denali Worldwide Royalty Option for such Collaboration Program, except as otherwise agreed by the Parties in writing.

### **4.3 Disclosure of Technology for Development Purposes.**

**4.3.1** Promptly after the Option Exercise Date for a particular Collaboration Program, Denali shall disclose and make available to Takeda the Regulatory Documentation, Denali Know-How, and Joint Program Know-How with respect to any Optioned Biologics or Optioned Products within the Collaboration Program, in each case that are Controlled by Denali and are necessary or reasonably useful for Takeda to Develop, Manufacture, or Commercialize such Optioned Biologics and Optioned Products within such Collaboration Program in the

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Territory in accordance with the terms of this Agreement. The JPT shall establish a process pursuant to which, after the Effective Date, but before Denali exercises the Denali Worldwide Royalty Option with respect to any Collaboration Program, the Parties shall disclose and make available to the other Party: Regulatory Documentation, Denali Know-How or Takeda Know-How (including, in each case, any Joint Program Know-How), and other Information claimed or covered by any Denali Patent, Takeda Patent, or Joint Program Patent or otherwise relating, directly or indirectly, to Optioned Biologics and Optioned Products within such Collaboration Program, in each case to the extent Controlled by such Party and that are necessary or reasonably useful for the other Party to Develop, Manufacture, or Commercialize such Optioned Biologics and Optioned Products within such Collaboration Program in the Territory in accordance with the terms of this Agreement, to the extent such items have not previously been provided to the other Party. The Parties shall cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchanges of Regulatory Documentation, Information, or inventions contemplated under this Section 4.3.1.

**4.3.2** After the Option Exercise Date for a particular Collaboration Program, each Party shall, to the extent requested by the other Party, provide such other Party with all reasonable assistance required in order to transfer to the other Party the Regulatory Documentation, Denali Know-How and Takeda Know-How (including, in each case, any Joint Program Know-How), and other Information required to be provided pursuant to Section 4.3.1, in each case in a timely manner, and shall assist the other Party with respect to the Exploitation of any Optioned Biologic and any Optioned Products within the relevant Collaboration Program in accordance with the terms of this Agreement; *provided* that such Party's requirement to provide the other Party any tangible items, including any documentation, shall be limited to those items then-existing and Controlled by such Party at the time of such request by the other Party; *provided, further*, that in the event Denali exercises the Denali Worldwide Royalty Option with respect to any Collaboration Program, Takeda shall not be required to make such Regulatory Documentation, Takeda Know-How (including any Joint Program Know-How), or other Information available to Denali. Without limiting the foregoing, prior to Denali's exercise of the Denali Worldwide Royalty Option, if visits of a Party's representatives to the other Party's facilities are reasonably requested by the other Party for purposes of transferring such Regulatory Documentation, Denali Know-How, Takeda Know-How, Joint Program Know-How, or other Information Controlled by a Party to the other Party or for purposes of the other Party acquiring expertise on the practical application of such Information or assisting on issues arising during such Exploitation, such Party shall use Commercially Reasonable Efforts to [\*\*\*].

**4.3.3** Any Out-of-Pocket Costs incurred by the Parties in performing disclosure and transfer activities pursuant to this Section 4.3, and if any supplies of Optioned Biologics or Optioned Product are transferred to the other Party in connection with such activities, the Manufacturing Cost of such materials shall be included as Development Costs; provided that following the Co-Funding End Date after Denali exercises the Denali Worldwide Royalty Option for a particular Collaboration Program, each Party will be solely responsible for all FTE Costs and Out-of-Pocket Costs it incurs to conduct such activities, except that Takeda shall reimburse the Manufacturing Cost of any materials supplied by Denali to Takeda. In addition, notwithstanding the above, neither Party shall be obligated to provide or make available to the other Party research tools, materials or Information generally applicable to Development of products for the treatment of diseases or conditions, to the extent such items are not reasonably necessary for the other Party to further Develop or Manufacture the applicable Optioned Biologics or Optioned Products in the Territory under this Agreement.

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#### 4.4 Regulatory Matters.

**4.4.1 Regulatory Lead.** Effective from and after the Option Exercise Date for a given Optioned Product (and any Optioned Biologic therein) on an Indication-by-Indication and jurisdiction-by-jurisdiction basis: (a) Denali shall be the Regulatory Lead until the commencement of regulatory activities related to the Late Stage Development Activities with respect to such Optioned Product (or, if earlier, Denali's exercise of the Denali Worldwide Royalty Option with respect to the applicable Collaboration Program); (b) Takeda shall be the Regulatory Lead beginning on commencement of regulatory activities related to the Late Stage Development Activities for such Optioned Product [\*\*\*]; and (c) on a jurisdiction-by-jurisdiction basis, the Commercial Lead shall be the Regulatory Lead [\*\*\*].

**4.4.2 Regulatory Activities.** The following shall apply with respect regulatory activities relating to each Collaboration Program:

(a) Subject to Section 4.4.2(c) below, the then-Regulatory Lead shall have the lead role and responsibility with respect to the preparation, obtaining and maintenance of all Regulatory Documentation necessary to perform the applicable activities under the applicable Development Plan or Commercialization Plan. The Non-Regulatory Lead shall support the Regulatory Lead, as may be reasonably necessary, in the preparation, obtaining and maintenance of such Regulatory Documentation, and in the activities in support thereof, including providing necessary documents or other materials required by Applicable Law to obtain such Regulatory Approvals, in each case in accordance with the terms and conditions of this Agreement and the applicable Development Plan. Notwithstanding the foregoing, to the extent the Regulatory Lead is not the same Party as the Manufacturing Lead, the Manufacturing Lead shall prepare the CMC Module 3 of the Common Technical Document in English for the Optioned Product, and the Regulatory Lead will modify as appropriate, such module for use in Regulatory Approvals in the Territory. Notwithstanding anything to the contrary in this Section 4.4.2(a), during the period of time when (i) Denali is the Regulatory Lead pursuant to Section 4.4.1(a), Takeda shall, to the extent permissible under Applicable Law and notwithstanding Section 4.4.2(d), have the right to interact directly with the respective Regulatory Authority on an interaction directly related to the filing and preparation of Regulatory Documentation for the Late Stage Development Activities, subject to prior notification and coordination with Denali, and (ii) Takeda is the Regulatory Lead pursuant to Section 4.4.1(b), if Denali is to be the Commercial Lead in the United States with respect to a Collaboration Program, (A) Denali shall, to the extent permissible under Applicable Law, have the right to interact directly with the FDA on the Product Labeling for each Optioned Product in such Collaboration Program, subject to prior notification and coordination with Takeda, (B) Takeda shall not conduct any scheduled discussions, meetings, and conferences with the FDA on Product Labeling for Optioned Products included in such Collaboration Program without prior notification and coordination with Denali, and (C) notwithstanding Section 4.4.2(d), Denali shall have the right to have [\*\*\*], or more if determined by the JPT, participate in all scheduled discussions, meetings, and conferences with the FDA on Product Labeling for each Optioned Product in such Collaboration Program for which Denali is to be the Commercial Lead in the United States pursuant to Section 4.4.2(d).

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(b) All Regulatory Documentation to the extent relating to an Optioned Biologic or Optioned Product with respect to an Indication within such Collaboration Program shall be owned by, and shall be the sole property and held in the name of the then-Regulatory Lead for such Indication. All Regulatory Documentation relating to the Optioned Biologics or Optioned Products that is not specific to any particular Indication shall be owned by, and shall be the sole property and held in the name of the then-Regulatory Lead for first Indication for which the applicable Optioned Biologics or Optioned Product received Regulatory Approval, or if no such Regulatory Approval has been obtained, the most advanced Indication with respect to the applicable Optioned Biologic or Optioned Product. In the event one Party replaces the other Party as the Regulatory Lead, the Parties shall, in manner consistent with the Transition Plan: (i) transition to such Regulatory Lead all applicable INDs for an Optioned Product; (ii) hereby assign to such Regulatory Lead all of such other Party's right, title and interest in and to all Regulatory Documentation (to the extent consistent with the above provisions of this Section 4.4.2(b) regarding ownership of such Regulatory Documentation) in the Territory and Controlled by such other Party during the Term; and (iii) duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary under, or as such Regulatory Lead may reasonably request to carry out more effectively the purpose of this Section 4.4.2(b).

(c) The Regulatory Lead in a Major Market for the applicable Optioned Biologics and Optioned Products shall provide the Non-Regulatory Lead with an opportunity to review and comment on all INDs, pre-meeting submissions, Drug Approval Applications, Product Labeling, material labeling supplements, Regulatory Authority meeting requests, core data sheets and other material regulatory submissions, in each case, in the Major Markets (collectively, "**Major Regulatory Filings**"). The Regulatory Lead shall consider in good faith the Non-Regulatory Lead's comments and use reasonable efforts to implement such comments. The Regulatory Lead shall provide access to interim drafts of such Major Regulatory Filings to the Non-Regulatory Lead via the access methods (such as secure databases) established by the JPT, and the Non-Regulatory Lead shall provide its comments on the final drafts of such Major Regulatory Filings or of proposed material actions within [\*\*\*] Business Days (or [\*\*\*] Business Days in the case of Drug Approval Applications), or such other period of time mutually agreed to by the Parties. In the event that a Regulatory Authority in the Territory establishes a response deadline for any such Major Regulatory Filing (or material action with respect thereto) shorter than such [\*\*\*]-Business Day period (or [\*\*\*]-Business Day period in the case of Drug Approval Applications), the Parties shall work cooperatively to ensure the Non-Regulatory Lead has a reasonable opportunity for review and comment within such deadlines. The Regulatory Lead shall consider in good faith any such comments of the Non-Regulatory Lead. Without limiting the foregoing, if Denali has elected to be the Commercial Lead in the United States for a particular Collaboration Program, all Drug Approval Applications to be filed in the United States for Optioned Products included in such Collaboration Program shall be drafted and prepared in close consultation with Denali.

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(d) The Regulatory Lead shall provide the Non-Regulatory Lead with prior written notice, to the extent the Regulatory Lead has advance knowledge, of any scheduled substantive meeting, conference, or discussion (including any advisory committee meeting) with a Regulatory Authority in the Major Markets relating to an Optioned Product within such Collaboration Program, within [\*\*\*] Business Days after the Regulatory Lead first receives notice of the scheduling of such substantive meeting, conference, or discussion (or within such shorter period as may be necessary in order to give the Non-Regulatory Lead a reasonable opportunity to attend such meeting, conference, or discussion). Subject to Section 4.4.2(a), the Non-Regulatory Lead shall have the right to have [\*\*\*] or more of its employees attend as an observer(s) (but not participate in) all such substantive meetings, conferences, and discussions.

(e) All costs incurred after the Option Exercise Date with respect to regulatory activities for to a particular Collaboration Program shall be a Development Cost or Allowable Expense, as appropriate; provided that from and after the Co-Funding End Date following Denali's exercise of the Denali Worldwide Royalty Option with respect to such Collaboration Program, each Party shall be solely responsible for all such costs incurred by such Party.

(f) The preceding sub-sections (c) and (d) will not apply to any Collaboration Program after Denali's exercise of the Denali Worldwide Royalty Option with respect to such Collaboration Program.

**4.4.3 Regulatory Data.** To the extent not provided pursuant to Section 4.3.1, the JPT shall establish a process pursuant to which each Party shall promptly provide to the other Party copies of or access to non-clinical data and Clinical Data, and other Information, results, and analyses with respect to any Development activities for a Collaboration Program and its Additional Development Activities (collectively, "**Regulatory Data**").

**4.5 Records.** Each Party shall maintain records in accordance with its standard practices, which in cases shall be consistent with standard practices in the pharmaceutical industry and in compliance with Applicable Law. Such records shall be retained by such Party for at least [\*\*\*] years after the Calendar Year to which such records relate, or for such longer period as may be required by Applicable Law. Upon request, such Party shall provide copies of the records it has maintained pursuant to this Section 4.5 to the other Party.

**4.6 Clinical Trial Register and Data Transparency.** The JPT will cooperate to establish timelines and procedures for reviewing any public disclosure of Clinical Data. The Development Lead will, in accordance with Applicable Law and its internal data transparency policies, publish the results or summaries of Clinical Studies relating to an Optioned Biologic or Optioned Product on a clinical trial register maintained by it and the protocols of clinical trials relating to such Optioned Biologic or Optioned Product on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) (or an equivalent register, or as otherwise required by Applicable Law or such Party's policies). In the event that the data transparency policies of the other Party (regardless if such policy is based upon Applicable Law or other internal guidelines) are materially different to the data transparency policies of the Development Lead, the JPT shall meet in good faith to resolve such material differences, *provided* that neither Party shall be permitted to prevent the disclosure of data by the other Party as required by such other Party's data transparency policies.

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**4.7 Patient Samples.** All patient samples collected and retained in connection with Clinical Studies involving an Optioned Biologic or Optioned Product that are performed under a Development Plan or for which costs are shared as Development Costs (together with compilations of Information comprising annotations regarding patient histories or correlating patient outcomes, with respect to such samples, “**Patient Samples**”) shall be a shared resource of the Parties. Unless otherwise agreed by the Parties or otherwise set forth in this Section 4.7, all Patient Samples shall be maintained and stored at the facilities of a Third Party reasonably agreed by the Parties for the purposes of the conduct of Collaboration Program activities, and the fees paid to such Third Party in connection with such maintenance and storage shall be a Development Cost. Each Party’s use of Patient Samples shall be in accordance with Applicable Law, including any informed consent and institutional review board regulations and all applicable requirements relating to the protection of human subjects. [\*\*\*].

## **ARTICLE 5 MANUFACTURING**

**5.1 Manufacturing Activities.** The Manufacturing Lead shall be responsible for Manufacturing or having Manufactured (using a reputable Third Party Provider) each Research Biologic, Optioned Biologic and Optioned Product, as applicable. The Manufacturing Lead shall use Commercially Reasonable Efforts to [\*\*\*]. The Manufacturing Lead shall obtain supply of the required quantities of Optioned Biologics, Optioned Product and placebo used in Clinical Studies, or otherwise to support the Development activities to be conducted under a Development Plan, either by performing Manufacturing by itself or through its Affiliates, or from a reputable Third Party Provider of manufacturing services, in each case until [\*\*\*]. Following [\*\*\*], the Manufacturing Lead will have the sole right to determine which of its or a Third Party Provider’s manufacturing sites will be used to manufacture the Optioned Product or component of the Optioned Product and may transfer the Manufacturing from one site to another, so long as such transfer would not reasonably be likely to have a material adverse effect on continued supply or, unless Denali has exercised the Denali Worldwide Royalty Option with respect to the Optioned Product, [\*\*\*] increase in costs incurred in connection with or as a result of such transfer. Notwithstanding the foregoing, prior to any such transfer, the Manufacturing Lead will notify the Non-Manufacturing Lead of its intention to transfer Manufacturing from one site to another and shall permit the Non-Manufacturing Lead to carry out an audit of the proposed new site before such transfer takes place. In the event that the Manufacturing Lead [\*\*\*] then, at the request of the Non-Manufacturing Lead, [\*\*\*].

**5.2 Manufacturing Lead.** Denali shall be the Manufacturing Lead for each Research Program and Collaboration Program until the completion of the transfer of Manufacturing responsibilities to Takeda in accordance with this Section 5.2 and Section 5.6. If (a) Denali exercises the Denali Worldwide Royalty Option for such Collaboration Program or (b) Denali proposes to the JPT and the JPT agrees [\*\*\*] that Denali should transfer Manufacturing Lead responsibilities to Takeda for such Collaboration Program following Takeda’s exercise of the Option, provided that no such JPT agreement or [\*\*\*] shall be required where such Manufacturing is performed by one or more Third Party Providers, then in each case the JPT will

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prepare, for the Parties' approval, a plan for the Manufacturing Technology Transfer consistent with Section 5.6 (the "**Manufacturing Transfer Plan**") to transfer Manufacturing responsibilities for such Collaboration Program to Takeda, after which Takeda shall become the Manufacturing Lead with respect to such Collaboration Program. Without limiting the foregoing, Takeda shall not become the Manufacturing Lead with respect to any Collaboration Program until the completion of the applicable Manufacturing Transfer Plan.

**5.3 Manufacturing Costs.** Subject to Section 1.52.2, Denali shall be solely responsible for all Manufacturing Costs incurred in furtherance of the applicable Research Plan. All Manufacturing Costs incurred in furtherance of a Development Plan or Commercialization Plan for a Collaboration Program shall be a Development Cost or Allowable Expense, as appropriate; *provided* that if Denali exercises the Denali Worldwide Royalty Option for a particular Collaboration Program, Takeda shall, following the Co-Funding End Date, bear all Manufacturing Costs and, to the extent that Denali is the Manufacturing Lead, shall reimburse Denali for its FTE Costs and Out-of-Pocket Costs incurred in connection with the Manufacture of Optioned Biologics and Optioned Products. The Manufacturing Lead will promptly inform the JPT of any circumstance which could reasonably be expected to result in a [\*\*\*] or greater increase in the Manufacturing Costs for any Optioned Biologic or Optioned Product during the Calendar Years covered by any then-current applicable budgets. The JPT will discuss any reasonable recommendations that either Party may have to mitigate against such increase to the Manufacturing Costs.

**5.4 Supply Agreements.** If, in a given country or region, the Development Lead or the Commercial Lead are a different Party than the Manufacturing Lead for clinical supply of Phase III Trials or Commercialization use, then, upon either Party's request, the Parties shall enter into separate supply and associated quality agreements (each, a "**Supply and Quality Agreement**") covering the terms of supply to the Non-Manufacturing Lead for such Development or Commercialization activities. The Supply and Quality Agreement will contain terms and conditions that are reasonable and customary for agreements of such nature, including a right of the Non-Manufacturing Lead to include its Manufacturing Costs as Development Costs or Allowable Expenses, as applicable. If the Parties are unable to reach agreement on such provisions within [\*\*\*] days of a request by either Party to enter into a Supply and Quality Agreement (which [\*\*\*]-day period may be extended upon the mutual agreement of the Parties), upon request by either Party, the same shall be determined pursuant to Section 16.6.4. The terms of any such Supply and Quality Agreement, including the Manufacturing Lead's rights and the Non-Manufacturing Lead's obligations under such Supply and Quality Agreement, shall be consistent with rights of the Manufacturing Lead under the applicable CMO Supply Agreements. To the extent there is any conflict between the terms and conditions of such Supply and Quality Agreements and this Agreement with respect to the matters expressly covered by such Supply and Quality Agreements, then such Supply and Quality Agreements shall control.

**5.5 Third Party Providers.** If a Manufacturing Lead utilizes one or more Third Party Providers to supply Optioned Product to the Non-Manufacturing Lead, then with respect to activities covered by any CMO Supply Agreement entered into prior to the Effective Date or, if entered into after the Effective Date, in accordance with the penultimate sentence of this Section 5.5, and so long as the Manufacturing Lead uses Commercially Reasonable Efforts to [\*\*\*]. If, after the Effective Date, the Manufacturing Lead enters into any agreements with Third

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Party Providers for Manufacturing services for clinical or Commercial supply of Optioned Biologics or Optioned Products under this Agreement, (a) the Manufacturing Lead shall [\*\*\*] and (b) the Manufacturing Lead shall [\*\*\*]. For clarity, the Manufacturing Lead is not required to [\*\*\*].

## 5.6 Manufacturing Transfer.

**5.6.1 Initial Transfer.** In the event Takeda is to be the Manufacturing Lead with respect to any Collaboration Program, the Parties shall design the Manufacturing Transfer Plan such that the Takeda will become the Manufacturing Lead for such Collaboration Program as soon as possible after Takeda is appointed to become the Manufacturing Lead, *provided* that if such Manufacturing Technology Transfer solely involves the transfer of responsibility for manufacturing activities being conducted by a Third Party Provider under a CMO Supply Agreement from one Party to the other without changing the manufacturing facility, such Manufacturing Transfer Plan shall be completed within [\*\*\*] or shall otherwise be completed within the time period specified in the applicable Manufacturing Transfer Plan. No Manufacturing Transfer Plan shall require Takeda to assume any CMO Supply Agreements between Denali and its Third Party Provider for Manufacturing activities for the relevant Collaboration Program unless Takeda consents to do so. In such instance, Denali shall, in accordance with the applicable Manufacturing Transfer Plan, [\*\*\*]. In the event any such CMO Supply Agreement cannot [\*\*\*], Denali shall use Commercially Reasonable Efforts to [\*\*\*]. In the event the assignment of any such CMO Supply Agreement is conditioned (other than for notice), the Parties shall discuss such conditions in good faith and, if the Parties, mutually agree to satisfy such conditions for the assignment of the applicable CMO Supply Agreement, the Manufacturing Transfer Plan shall address such matter. As further provided in the Manufacturing Transfer Plan, Denali shall cooperate with Takeda with respect to such other steps as may be reasonably required to effect a full transfer to Takeda or Takeda's Third Party Provider of all Denali Know-How (including any Joint Program Know-How) that are necessary or reasonably useful for Takeda to implement the then-current process for the Manufacture of such Optioned Product and Optioned Biologic (the "**Manufacturing Process**") (together with the assignment of CMO Supply Agreements and enablement and assistance to enter into a new agreement with such Third Party Provider, the "**Manufacturing Technology Transfer**"). As a part of the Manufacturing Technology Transfer, Denali shall cause all appropriate employees and representatives of Denali and its Affiliates, and appropriate analytical and quality control employees and representatives of its Third Party Providers, at mutually convenient times, to meet with, employees or representatives of Takeda or its designated Third Party Provider at the applicable manufacturing facility: (a) to assist with the working up and use of the Manufacturing Process and with any training to the extent reasonably necessary to enable the use and practice the Manufacturing Process; and (b) to make available all necessary equipment Controlled by Denali, to support and execute the transfer of all applicable analytical methods and the validation thereof (including, all applicable Denali Know-How, Joint Program Know-How, methods, validation documents, manufacturing and release enabling reports, and other documentation, materials and sufficient supplies of all primary and other reference standards).

**5.6.2 Subsequent Transfers.** Without limiting the foregoing, after completion of the Manufacturing Transfer Plan, Denali shall, and shall use Commercially Reasonable Efforts to [\*\*\*], provided that Denali shall use Commercially Reasonable Efforts to

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obtain such rights) to take the following actions, in each case, as reasonably requested by Takeda:

(a) make available, to Takeda or its designated Third Party Provider from time to time, all Manufacturing-related Denali Know-How, Joint Program Know-How, Information and materials relating to the Manufacturing Process Controlled by Denali and not transferred to Takeda or such Third Party Provider during the initial transfer, and all documentation constituting material support, performance advice, shop practice, standard operating procedures, specifications as to materials to be used and control methods, that are Controlled by Denali and reasonably necessary to enable Takeda or its designated Third Party Provider to use and practice the Manufacturing Process; and

(b) provide such other assistance as Takeda, or designated its Third Party Provider, as applicable, may reasonably request to enable Takeda or its designated Third Party Provider to use and practice the Manufacturing Process and otherwise to Manufacture the applicable Optioned Biologics and Optioned Products.

**5.6.3 Transfer Costs.** All FTE Costs and Out-of-Pocket Costs incurred by either Party in performing activities pursuant to this Section 5.6, including Manufacturing Technology Transfer activities and activities under Section 5.6.2, shall be included as Development Costs or Allowable Expenses, as applicable.

**5.6.4 Third Party Agreements.** Notwithstanding anything to the contrary in this Agreement, each Manufacturing Transfer Plan and any Manufacturing Technology Transfer shall be subject to the terms and conditions of the agreements between the Manufacturing Lead and its applicable Third Party Providers of manufacturing services and technology (each agreement, a “**CMO Supply Agreement**”). A list of CMO Supply Agreements existing as of the Execution Date are set forth on Schedule 5.6.4.

## ARTICLE 6 COMMERCIALIZATION

**6.1 General.** Subject to the terms of this Agreement, following Takeda’s exercise of its Option with respect to a particular Collaboration Program, the JPT (and the JSC, as applicable) shall oversee and, to the extent applicable, coordinate, the Commercialization of all Optioned Products within such Collaboration Program in the Field in the Territory.

### 6.2 Commercialization Activities.

**6.2.1 Efforts.** With respect to each Collaboration Program, for each jurisdiction in which Regulatory Approval is obtained, each Party shall use Commercially Reasonable Efforts to [\*\*\*]. Each Commercialization Plan for a Collaboration Program shall reflect Commercially Reasonable Efforts to [\*\*\*]. Each Party shall perform any and all of its Commercialization activities with respect to each Collaboration Program, in good scientific manner and in compliance with all Applicable Law.

**6.2.2 Allocation of Activities and Costs.** For each Collaboration Program, each Party shall be responsible for day-to-day implementation of the Commercialization

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activities with respect to the Optioned Products within such Collaboration Program allocated to such Party under the applicable Commercialization Plan. Unless otherwise agreed by the Parties, the Commercial Lead shall have the responsibilities set forth in Sections 6.2.3 and 6.2.4. The Parties shall share all FTE Costs and Out-of-Pocket Costs incurred in connection with Commercialization activities to the extent included in Allowable Expenses; provided that following the Co-Funding End Date after Denali exercises the Denali Worldwide Royalty Option for a particular Collaboration Program, each Party will be solely responsible for all FTE Costs and Out-of-Pocket Costs it incurs to conduct Commercialization activities for such Collaboration Program, except as otherwise agreed by the Parties in writing.

**6.2.3 Commercial Lead.** Takeda shall be the Commercial Lead for each Collaboration Program in the Territory; *provided however*, that if Denali has not exercised the Denali Worldwide Royalty Option with respect to at least [\*\*\*], Denali shall have the option to be designated as the Commercial Lead in the United States for the [\*\*\*] for which Denali does not exercise the Denali Worldwide Royalty Option through the Development program. For clarity, Denali shall not be the Commercial Lead for the first commercial Collaboration Program. Denali may exercise such option by notifying Takeda and the JPT in writing of its election prior to [\*\*\*]. If Denali issues a notice of its election to be the Commercial Lead in accordance with this Section 6.2.3 and a [\*\*\*]. For clarity, if Denali does not timely issue its notice of election to be the Commercial Lead in the United States with respect to any Collaboration Program, Takeda shall be the Commercial Lead worldwide with respect to such Collaboration Program.

**6.2.4 Co-Commercialization in the Co-Commercialization Territory.** The Non-Commercial Lead in each country of the Co-Commercialization Territory for any Collaboration Program shall have the option to co-Commercialize the Optioned Products under such Collaboration Program in each country of the Co-Commercialization Territory by providing the Commercial Lead with written notification of its exercise of such option at least [\*\*\*] months prior to the anticipated date of the first Regulatory Approval for the first Optioned Product under such Collaboration Program; *provided* that Denali shall not have the right to exercise such co-commercialization option with respect to any Collaboration Program for which Denali has exercised the Denali Worldwide Royalty Option. The Non-Commercial Lead may conduct Details with respect to Optioned Products, Phase IV Studies, and certain other marketing, promotional, and medical affairs activities with respect to Optioned Products, in each case, in a manner consistent with the Co-Commercialization Plan; *provided* that the Non-Commercial Lead shall not conduct greater than [\*\*\*] of any such activities. The Commercial Lead shall consider in good faith the Non-Commercial Lead's views on pricing of the Optioned Products included in such Collaboration Program through the JPT, for each Collaboration Program for which Denali has not exercised the Denali Worldwide Royalty Option. For clarity, the Non-Commercial Lead shall not be allocated responsibilities with respect to regulatory and compliance matters, warehousing or distribution, sales, booking sales or reimbursement for the applicable Optioned Product, unless requested by the Commercial Lead and agreed to by such Non-Commercial Lead.

**6.2.5 Commercialization Reports.** For each Collaboration Program, each Party shall report on the Commercialization activities such Party has performed (or caused to be performed) under such Collaboration Program in accordance with the procedures established by the JPT. The JPT shall evaluate the work performed in relation to the goals of the applicable Commercialization Plan. Each Party shall provide such other Information as reasonably requested by the JPT.

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**6.2.6 Supply Forecast.** The Commercial Lead shall prepare quarterly, non-binding forecasts for the quantities of Optioned Product necessary pursuant to the applicable Commercialization Plan and shall provide such forecast to the applicable JPT for review at each JPT meeting.

### **6.3 Commercialization Plans.**

**6.3.1 Global Commercialization Plan.** Reasonably in advance of the first Regulatory Approval for the first Optioned Product within a Collaboration Program, the Commercial Lead shall prepare for the JPT's discussion, review and finalization a Global Commercialization Plan for such Collaboration Program in reasonable scope, as well as a corresponding Commercialization Budget for such Global Commercialization Plan that complies with the requirements of this Agreement. The JPT shall present such plan to the JSC for approval. The JPT shall agree upon the appropriate level of detail to be included in the respective Global Commercialization Plan; *provided* that if Denali has exercised the Denali Worldwide Royalty Option with respect to such Collaboration Program, the Global Commercialization Plan shall be limited to material Commercialization activities in Major Markets with a high-level budget for such activities.

**6.3.2 Exclusive Market Commercialization Plan.** For each Collaboration Program for which Denali has not exercised the Denali Worldwide Royalty Option, the Commercial Lead shall also prepare, for the JPT's approval, an Exclusive Market Commercialization Plan, which shall be consistent with the Global Commercialization Plan for such Collaboration Program. The JPT shall agree upon the appropriate level of detail to be included in the respective Exclusive Market Commercialization Plan, taking into consideration the relative size and commercial potential of the applicable Major Market.

**6.3.3 Co-Commercialization Plan.** For each Collaboration Program for which Denali has not exercised the Denali Worldwide Royalty Option and for each country which the Non-Commercial Lead has exercised the co-commercialization option under [Section 6.2.4](#), the Commercial Lead shall prepare, in consultation with the Non-Commercial Lead in each country and for the JPT's discussion, review and finalization, a Co-Commercialization Plan for such Collaboration Program. The JPT shall present such plan to the JSC for approval. Each Co-Commercialization Plan shall be consistent with the Global Commercialization Plan for the applicable Collaboration Program and shall include a corresponding Commercialization Budget for the activities covered by such Co-Commercialization Plan. Each Co-Commercialization Plan shall allocate such Commercialization activities between the Parties, taking into consideration the Parties' respective actual or reasonably anticipated capabilities, infrastructure and resources in each of the United States and China, as the case may be, relevant to the applicable Optioned Product at the time of expected First Commercial Sale in accordance with the terms of this Agreement.

**6.3.4 Amendments and Updates.** The JPT shall review the Commercialization Plans (including, if applicable, the associated Commercialization Budgets)

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on a regular basis, and in no event less frequently than once each Calendar Year (as provided below), or more frequently as needed to take into account completion, commencement or cessation of Commercialization activities contemplated in the then-current applicable Commercialization Plan for, as well as any newly available Information related to, such Collaboration Program. Either Party, through its representatives on the JPT, may propose amendments to a Commercialization Plan (and/or, if applicable, the associated Commercialization Budget) for a given Collaboration Program from time to time. Any and all amendments to the Global Commercialization Plan or the Co-Commercialization Plan shall be subject to approval in accordance with Section 2.3.6. Any and all amendments to an Exclusive Market Commercialization Plan shall be approved by the JPT. In any event, an updated Commercialization Plan, including the associated Commercialization Budget (if applicable), shall be provided by the JPT (and approved by the JSC as required) no later than November 1 of each Calendar Year. If such revised Commercialization Plan (and associated Commercialization Budget (if applicable)) is not approved by the JSC by December 1 of a Calendar Year, then, until such time as such a revised Commercialization Plan (and associated Commercialization Budget (if applicable)) is approved in accordance with Section 2.3.6: (a) the then-current Commercialization Plan (and associated Commercialization Budget (if applicable)) for the relevant territory shall continue to govern the Parties' commercialization activities under this Agreement with respect to the applicable Collaboration Program; and (b) each Party shall be permitted to conduct the activities allocated to such Party in such then-current Commercialization Plan and to incur costs consistent with such associated Commercialization Budget, which costs shall be shared by the Parties as Allowable Expenses in accordance with Section 8.6.

#### **6.4 Sales Representatives.**

**6.4.1** Denali and Takeda shall each ensure that its sales representatives do not make any representation, statement, warranty or guaranty with respect to an Optioned Product that is not consistent with the applicable, current package insert of prescribing information or other documentation accompanying or describing such Optioned Product, including mutually approved limited warranty and disclaimers, if any. Denali and Takeda shall each ensure that its sales representatives do not make any statements, claims or undertakings to any person with whom they discuss or promote Optioned Products that are not consistent with, nor provide or use any labeling, literature or other materials other than, those Promotional Materials currently approved for use by the JPT in the Co-Commercialization Territory. If at any time the Commercial Lead no longer approves the use of specified Promotional Materials in any country of the Co-Commercialization Territory, each Party shall take appropriate action to remove the Promotional Materials from use destroy such Promotional Materials or otherwise modify such Promotional Materials for an approved use.

**6.4.2** Notwithstanding the foregoing, in the event the Non-Commercial Lead is co-Commercializing the Optioned Products in any country within the Co-Commercialization Territory, the Non-Commercial Lead shall have the right to review and comment on the training materials and programs to be used in such markets prior to the implementation of such training materials and programs, in accordance with the process established by the JPT, and the Commercial Lead shall give good faith consideration to the Non-Commercial Lead's comments regarding the training materials and programs, including any comments related to the training materials and programs compliance with Applicable Law.

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**6.4.3** Denali and Takeda shall each cause its sales representatives to comply with Applicable Law and industry guidelines related to the performance of its obligations hereunder.

**6.4.4** Each Party shall maintain records of its sales representatives' activities in the Territory and each Party shall allow representatives of the other Party to inspect such records upon request during normal business hours and upon reasonable prior notice; *provided* that Denali shall no longer have such right with respect to a particular Collaboration Program after it exercises the Denali Worldwide Royalty Option with respect to such Collaboration Program.

**6.4.5** If Denali is the Non-Commercial Lead and exercises its co-Commercialization rights in any country of the Co-Commercialization Territory in accordance with Section 6.2.3, the applicable Co-Commercialization Plan shall provide for sales representatives of each Party to be deployed to major metropolitan areas.

**6.4.6 Calculation of Sales Force Costs.** For the purposes of calculating the FTE Costs of each Party's sales representatives performing activities under the applicable Co-Commercialization Plan, the FTE Rate shall be deemed to be [\*\*\*] of the applicable mutually agreed FTE Rate for such sales representative on a full-time basis; *provided* that for each sales representative who also engages in promotion activities for a product other than an Optioned Product during the relevant Calendar Quarter, the cost of such sales representative (for purposes of calculating Allowable Expenses), shall be reduced proportionately based on the Detail position of such other product(s) during such sales activities and a reasonable apportionment of the value of such Detail position(s) for such other product(s). For such purposes: (i) in a two-product Detail, the first position Detail shall be deemed [\*\*\*] and the second position shall be deemed [\*\*\*] of the value of the product Detail; (ii) in a three-product Detail, the first position Detail shall be deemed [\*\*\*], the second position shall be deemed [\*\*\*] and the third position shall be deemed [\*\*\*] of the value of the product Detail; and (iii) the value of other similar multi-product promotions shall be allocated in a similar way. For example, if a sales representative is promoting only an Optioned Product and no other products in a Calendar Quarter, [\*\*\*] of the FTE Rate for such sales representative shall be included for purposes of calculating the Allowable Expenses for such Calendar Quarter, and if such sales representative is promoting one other product and such other product is in the second Detail position, only [\*\*\*] of the FTE Rate for such sales representative shall be included in calculating the Allowable Expenses for such Calendar Quarter.

**6.5 Advertising and Promotional Materials.** The Commercial Lead for a particular Collaboration Program and territory shall develop relevant sales, promotion, market access and advertising materials relating to the Optioned Products within such Collaboration Program and territory (collectively, "**Promotional Materials**") in each case consistent with Applicable Law, the applicable Commercialization Plans and any determinations made by the JPT with respect to such matters pursuant to Section 2.2.2(c)(ix). The Commercial Lead shall be responsible for the medical, regulatory and legal review of Promotional Materials and for the interpretation and

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adherence to the Applicable Law governing the preparation and use of such Promotional Materials, including any advance review of the Promotional Materials required by the applicable Regulatory Authority. Notwithstanding the foregoing, in the event the Non-Commercial Lead is co-Commercializing the Optioned Products in any country within the Co-Commercialization Territory, the Non-Commercial Lead shall have the right to review and comment on the Promotional Materials to be used in such markets prior to the implementation of such Promotional Materials, in accordance with the process established by the JPT, and the Commercial Lead shall give good faith consideration to the Non-Commercial Lead's comments regarding the Promotional Materials, including any comments related to the Promotional Materials' compliance with Applicable Law. The Commercial Lead for each market will own all right, title and interest in and to any and all Promotional Materials for an Optioned Product for use in such market (except with respect to any Corporate Names of the other Party included in any Promotional Materials). The Non-Commercial Lead will execute all documents and take all actions as are reasonably requested by the Commercial Lead to vest title to such Promotional Materials in the Commercial Lead.

**6.6 Medical Inquiries.** The Commercial Lead shall handle all medical questions or inquiries from members of the medical profession in any country within the Co-Commercialization Territory regarding the Optioned Products. In the event the Non-Commercial Lead is co-Commercializing the Optioned Products a country within the Co-Commercialization Territory, the Non-Commercial Lead shall, and shall cause its sales representatives or medical science liaisons (as applicable depending on the nature of the question or inquiry) to, refer to the Commercial Lead all such questions and inquiries within [\*\*\*] hours of receipt, unless earlier notification is required pursuant to the Pharmacovigilance Agreement or Applicable Law. The Commercial Lead shall respond appropriately to all such inquires in a timely manner. The Parties' costs and expenses incurred in responding to medical questions and inquiries in accordance with this Section 6.6 shall be included in Allowable Expenses, unless Denali has exercised the Denali Worldwide Royalty Option for the relevant Collaboration Program.

**6.7 Optioned Product Packaging.** The Commercial Lead shall develop and approve packaging and Product Labeling for each Optioned Product, which in all cases shall be consistent with the applicable Commercialization Plan and in accordance with Applicable Law. The Parties' costs and expenses incurred in conducting such activities shall be included in Allowable Expenses, unless Denali has exercised the Denali Worldwide Royalty Option for the relevant Collaboration Program.

### **6.8 Sales and Distribution.**

**6.8.1 Booking Sales.** The Commercial Lead in any jurisdiction or region for a particular Collaboration Program shall (a) book all sales of Optioned Products and (b) be responsible for warehousing and distributing the Optioned Products in such jurisdiction or region. If the Non-Commercial Lead in a country or region for a particular Collaboration Program receives any orders for an Optioned Product, it shall refer such orders to the Commercial Lead for such Collaboration Program in the applicable country or region.

**6.8.2 Branding.** The Commercial Lead for each jurisdiction or region shall be responsible for determining positioning, messaging, and branding for each Optioned Product in

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such jurisdiction or region; provided, that positioning, messaging, and branding for each Optioned Product shall be consistent with the applicable Commercialization Plans, and Applicable Law. The Parties' costs and expenses incurred in conducting such activities shall be included in Allowable Expenses, unless Denali has exercised the Denali Worldwide Royalty Option for the relevant Collaboration Program.

**6.9 Shipping and Returns.** The Commercial Lead with for each jurisdiction or region shall be responsible for handling all returns of the Optioned Products in such jurisdiction or region. If an Optioned Product sold in a jurisdiction or region is returned to the Non-Commercial Lead, the Non-Commercial Lead shall promptly ship such Optioned Product to a facility designated by the Commercial Lead. The Commercial Lead for each jurisdiction or region shall also be responsible for handling all aspects of such Optioned Product order processing, invoicing and collection, distribution, inventory, and receivables for each jurisdiction or region. The Parties' costs and expenses incurred in conducting such activities shall be included in Allowable Expenses, unless Denali has exercised the Denali Worldwide Royalty Option for the relevant Collaboration Program.

**6.10 Recalls, Market Withdrawals or Corrective Actions.** In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with an Optioned Product, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, in each case, in any jurisdiction or region, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall within [\*\*\*] hours, advise the other Party thereof by orally or in writing Unless Denali has exercised the Denali Worldwide Royalty Option, the Commercial Lead, in consultation with the Non-Commercial Lead, shall decide whether to conduct a recall in such jurisdiction or region (except in the case of a government mandated recall, when the Commercial Lead may act without such advance notice or consultation but, shall notify the Non-Commercial Lead as soon as possible) and the manner in which any such recall shall be conducted. Each Party shall make available to the other Party, upon request, all of such Party's pertinent records that such other Party may reasonably request to assist such other Party in effecting any recall. The costs and expenses of any recall in the Territory shall be included in calculating Allowable Expenses, unless Denali has exercised the Denali Worldwide Royalty Option for the relevant Collaboration Program.

**6.11 Product Trademarks.** Subject to Section 6.12, Takeda shall have the sole right to determine and own the Product Trademarks to be used with respect to the Exploitation of the Optioned Products on a worldwide basis. Subject to any pre-existing Trademarks a Party may have, neither Party shall, directly or indirectly: (a) use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any Product Trademark; and (b) do any act which endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Product Trademarks. Each Party agrees to conform to the customary industry standards for the protection of Product Trademarks for products and such guidelines of Takeda with respect to manner of use (in the case of Denali, as provided in writing by Takeda) of the Product Trademarks. Without limiting any pre-existing Trademarks a Party may have, neither Party shall, directly or indirectly, attack, dispute, or contest the validity of or ownership of such Product Trademark anywhere in the Territory or any registrations issued or issuing with respect thereto.

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**6.12 Markings.** To the extent required by Applicable Law in a country or other jurisdiction in the Territory, the Promotional Materials, packaging, and Product Labeling for the Optioned Products used in connection with the Optioned Products in such country or other jurisdiction shall contain the Corporate Name of both the Commercial Lead and the Non-Commercial Lead.

**ARTICLE 7  
LICENSE GRANTS; EXCLUSIVITY**

**7.1 License Grants to Takeda.**

**7.1.1** Subject to the terms and conditions of this Agreement (including Section 7.1.4), with respect to each Designated Target, Denali hereby grants to Takeda a co-exclusive (with Denali) non-sublicensable (except in accordance with Section 7.3.1) license under the Denali Technology (including Denali's interest in the Joint Program Know-How and Joint Program Patents) solely to the extent necessary for Takeda to perform its obligations under the Research Plan for such Designated Target.

**7.1.2** Subject to the terms and conditions of this Agreement (including Section 7.1.4), and effective automatically on the Option Exercise Date with respect to a Collaboration Program, Denali shall grant and hereby grants to Takeda, with respect to the Designated Target of such Collaboration Program (referred to as the Optioned Target below):

(a) a co-exclusive (with Denali) license, with the right to grant sublicenses in accordance with Section 7.3.2, under the Denali Technology (including Denali's interest in the Joint Program Know-How and Joint Program Patents), to Exploit Optioned Biologics and Optioned Products Directed to such Optioned Target in the Field in the Territory in a manner consistent with the applicable Development Plan and the applicable Commercialization Plans;

(b) a co-exclusive (with Denali) license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 7.3.2, under the Regulatory Approvals and any other Regulatory Documentation that Denali may Control with respect to the Optioned Biologics or Optioned Products Directed to such Optioned Target to Exploit such Optioned Biologics and Optioned Products in the Field in the Territory in a manner consistent with the applicable Development Plan and the applicable Commercialization Plans; and

(c) a co-exclusive (with Denali) license, with the right to grant sublicenses in accordance with Section 7.3.2, to use Denali's Corporate Names solely as required by Applicable Law to Exploit Optioned Biologics or Optioned Products Directed to such Optioned Target in the Field in the Territory in a manner consistent with the applicable Development Plan and the applicable Commercialization Plans.

**7.1.3** Subject to the terms and conditions of this Agreement (including Section 7.1.4 and Section 7.8), Denali hereby grants to Takeda a non-exclusive, worldwide, perpetual, irrevocable, fully-paid, royalty-free license, with the right to grant sublicenses in



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accordance with Section 7.3.3, under any [\*\*\*] to Exploit [\*\*\*]. For clarity, the foregoing shall not include the grant by Denali to Takeda of a license under any [\*\*\*] to the extent Denali does not have the right to grant such license [\*\*\*].

**7.1.4 Certain Restrictions.** Notwithstanding any other provision of this Agreement, the rights and licenses granted to Takeda under this Agreement shall not include, or be deemed to include, [\*\*\*], except as expressly set forth in the Research Plan or as otherwise expressly agreed in writing in advance by the Parties. In no event shall Takeda use (or authorize the use of) any Denali Technology (other than Joint Program Know-How and Joint Program Patents) except for the purposes of [\*\*\*]. For clarity, notwithstanding Denali's co-exclusive rights with Takeda under this Agreement as set forth in Section 7.1 and Section 7.2, during the Term with respect to each Collaboration Program, Denali shall not have [\*\*\*]. For the avoidance of doubt, the co-exclusive rights granted by Denali to Takeda under this Agreement shall not prohibit Denali from Exploiting, and Denali shall retain all rights to Exploit, the [\*\*\*] and [\*\*\*] or [\*\*\*], or [\*\*\*] (other than any such [\*\*\*]), for any purpose, subject to [\*\*\*].

## **7.2 License Grants to Denali.**

**7.2.1** Subject to the terms and conditions of this Agreement, with respect to each Designated Target, Takeda hereby grants to Denali a co-exclusive (with Takeda), non-sublicensable (except in accordance with Section 7.3.4) license under the Takeda Technology (including Takeda's interest in the Joint Program Know-How and Joint Program Patents) solely to the extent necessary for Denali to perform its obligations under the Research Plan for such Designated Target.

**7.2.2** Subject to the terms and conditions of this Agreement, and effective automatically on the Option Exercise Date with respect to a particular Collaboration Program, Takeda shall grant and hereby grants to Denali, with respect to the Designated Target of such Collaboration Program (referred to as the Optioned Target below):

(a) a co-exclusive (with Takeda) license, with the right to grant sublicenses in accordance with Section 7.3.5, under the Takeda Technology (including Takeda's interest in the Joint Program Know-How and Joint Program Patents), to Exploit Optioned Biologics and Optioned Products Directed to such Optioned Target in the Field in the Territory in a manner consistent with the applicable Development Plan and the applicable Commercialization Plans;

(b) a co-exclusive (with Takeda) license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 7.3.5, under the Regulatory Approvals and any other Regulatory Documentation that Takeda may Control with respect to the Optioned Biologics or Optioned Products Directed to such Optioned Target to Exploit such Optioned Biologics and Optioned Products in the Field in the Territory in a manner consistent with the applicable Development Plan and the applicable Commercialization Plans; and

(c) a co-exclusive (with Takeda) license, with the right to grant sublicenses in accordance with Section 7.3.5, to use Takeda's Product Trademarks and Takeda's

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Corporate Names solely as required by Applicable Law to Exploit Optioned Biologics or Optioned Products Directed to such Optioned Target in the Field in the Territory in a manner consistent with the applicable Development Plan and the applicable Commercialization Plans.

**7.2.3** Without limiting Denali's rights under Section 9.1, subject to the terms and conditions of this Agreement (including Section 7.8 below), Takeda hereby grants to Denali a non-exclusive, worldwide, perpetual, irrevocable, fully-paid, royalty-free (subject to Section 7.5.2(d)) license, [\*\*\*], under Takeda's and/or any of its Affiliate's interest in any [\*\*\*] to [\*\*\*].

**7.2.4 Certain Restrictions.** In no event shall Denali use (or authorize the use of) any Takeda Technology (other than Joint Program Know-How and Joint Program Patents) except for the purposes of [\*\*\*]. For clarity, notwithstanding Takeda's co-exclusive rights with Denali under this Agreement as set forth in Section 7.1 and Section 7.2, Takeda shall not have the right to [\*\*\*].

### **7.3 Sublicenses.**

**7.3.1** Takeda shall have the right to grant sublicenses under the licenses granted to Takeda under Section 7.1.1, to its Affiliates (through multiple tiers) and Third Party Providers (without the right to grant further sublicenses) solely in accordance with Section 7.4; *provided* that any such sublicenses shall be materially consistent with the terms and conditions of this Agreement.

**7.3.2** Takeda shall have the right to grant sublicenses (or further rights of reference), through multiple tiers of sublicensees, under the licenses and rights of reference granted in Section 7.1.2, to its Affiliates and other Persons; *provided* that [\*\*\*]. Notwithstanding the foregoing, Takeda shall not, without Denali's prior written consent, grant to a Sublicensee any such sublicense or rights of reference with respect to [\*\*\*] (a) [\*\*\*], (b) [\*\*\*], or (c) unless such Sublicensee is a Significant Biopharmaceutical Company, [\*\*\*]. For such purposes, a "Significant Biopharmaceutical Company" means [\*\*\*].

**7.3.3** Subject to Section 7.8 below, Takeda shall have the right to grant sublicenses, through multiple tiers of sublicensees, under the licenses granted to Takeda under Section 7.1.3, to its Affiliates and other Persons; *provided* that [\*\*\*] and any such Person to whom Takeda grants such rights has agreed [\*\*\*].

**7.3.4** Denali shall have the right to grant sublicenses under the licenses granted to Denali under Section 7.2.1, to its Affiliates (through multiple tiers) and Third Party Providers (without the right to grant further sublicenses) solely in accordance with Section 7.4; *provided* that [\*\*\*].

**7.3.5** Denali shall have the right to grant sublicenses (or further rights of reference) under the licenses and rights of reference granted to Denali under Section 7.2.2 to its Affiliates and other Persons: (a) [\*\*\*]; (b) [\*\*\*]; or (c) otherwise solely in connection with the engagement of a subcontractor in accordance with Section 7.4 for the performance of the activities that Denali has the right to conduct in connection with a Collaboration Program under this Agreement.

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**7.3.6** Subject to Section 7.8 below, Denali shall have the right to grant sublicenses, through multiple tiers of sublicensees, under the licenses granted to Denali under Section 7.2.3, to [\*\*\*] and [\*\*\*]; *provided* that [\*\*\*] and [\*\*\*].

**7.3.7** Each sublicensing Party (or Party whose Affiliate grants a sublicense) shall [\*\*\*] and shall [\*\*\*].

**7.4 Subcontracting.** Each Party and its Affiliates may subcontract the performance of any of its research activities, Development activities and Commercialization activities in the Territory with respect to each Collaboration Program undertaken in accordance with this Agreement to one or more Third Party Providers pursuant to a Subcontract Agreement which shall be consistent with the terms of this Agreement; *provided*, that: (a) each Party shall [\*\*\*] and shall [\*\*\*]; and (b) the Subcontract Agreement shall (i) contain [\*\*\*] and (ii) provide such subcontracting Party [\*\*\*]. Notwithstanding the foregoing, the subcontracting Party shall [\*\*\*] and shall [\*\*\*].

## **7.5 Third Party Intellectual Property.**

### **7.5.1 Denali's In-License Agreement.**

(a) **Existing In-Licenses.** It is understood that Denali's In-License Agreements existing as of the Execution Date (collectively, the "**Existing In-License Agreements**") may require that particular provisions be incorporated into a sublicense granted thereunder. The text of any such provisions in the Existing In-License Agreements are set out on Schedule 7.5.1 attached hereto and shall be deemed incorporated by reference into this Agreement. Takeda agrees to be bound by the provisions set out on Schedule 7.5.1 to the extent applicable to Takeda in its capacity as a sublicensee under each such Existing In-License Agreement for so long as the applicable Existing In-License Agreement is in full force and effect and thereafter with respect to any surviving [\*\*\*] obligations, and, to the extent required by any such Existing In-License Agreement as of the Execution Date, the relevant Third Party licensor shall be deemed to be a third party beneficiary of this Agreement solely for the purposes of enforcing any of such Third Party licensor's rights against Takeda in its capacity as a sublicensee under such Existing In-License Agreement.

(b) **Denali New Technology.** If, after the Effective Date, Denali acquires from any Third Party subject matter within the Denali Technology to be applied to a Biologic(s) or Product(s) being Developed or Commercialized under this Agreement ("**Denali New Technology**"), the following shall apply: Denali shall [\*\*\*] and provide [\*\*\*]. In the event [\*\*\*], then such Denali New Technology shall [\*\*\*]. In the event [\*\*\*], then such Denali New Technology shall [\*\*\*].

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(c) **Payment Obligations for Denali's Product In-License Agreements.** If any Denali Technology or Denali New Technology is subject to payment to a Third Party under a Product In-License Agreement, the following shall also apply:

(i) Prior to the Option Exercise Date for a Collaboration Program and after the Option Exercise Date, except as set forth in clause (ii) below, Denali shall be responsible for any payments due to a Third Party under any Product In-License Agreement.

(ii) Following the Option Exercise Date for a particular Collaboration Program all amounts that become owing to such Third Party as a result of a Party's exercise of any such Denali Technology or Denali New Technology in performance of activities under this Agreement shall be included as Allowable Expenses, *provided that* [\*\*\*], *provided further* that if Denali has exercised the Denali Worldwide Royalty Option, such amounts shall be paid by Takeda but subject to Takeda's right to offset any such payment under Section 8.7.5(e) against royalty payments by Takeda to Denali.

(d) [\*\*\*].

(e) **Payment Obligations for Denali's Platform In-License Agreements.** If any Denali Technology or Denali New Technology is subject to payment to a Third Party under a Platform In-License Agreement [\*\*\*], the following shall apply:

(i) Prior to the Option Exercise Date for a Collaboration Program and after the Option Exercise Date, except as set forth in clause (ii) below, [\*\*\*].

(ii) Following the Option Exercise Date for a particular Collaboration Program, [\*\*\*].

(iii) Notwithstanding the foregoing in clauses (i) and (ii) above, if any subject matter included within a Platform In-License Agreement pertains to [\*\*\*], then the JSC shall [\*\*\*].

**7.5.2 Takeda's In-License Agreements.** If, after the Effective Date, Takeda wishes to acquire or actually acquires from any Third Party subject matter within the Takeda Technology to be applied to a Biologic(s) or Product(s) being Developed or Commercialized under this Agreement, or incorporate any Third Party subject matter already acquired by Takeda into any Biologic(s) or Product(s) being Developed or Commercialized under this Agreement (any such acquired subject matter, "**Takeda New Technology**"), the following shall apply:

(a) **Takeda New Technology that is** [\*\*\*]. For any subject matter that is [\*\*\*]. In such event, Denali shall [\*\*\*]. In the event that [\*\*\*]. For clarity, such Takeda New Technology shall be [\*\*\*].

(b) **Other Takeda New Technology.** For any other subject matter, Takeda shall so notify the JSC and provide the JSC with a summary of the terms of any license or agreement under which Takeda acquired such Takeda New Technology that would be applicable to such a Biologic(s) or Product(s). In the event the JSC agrees in writing to apply such Takeda New Technology to Biologic(s) or Product(s) under this Agreement, then such Takeda New Technology shall be included in Takeda Technology and subject to the terms and conditions of this Agreement. In the event the JSC does not agree in writing to apply such Takeda New Technology to Biologic(s) or Product(s), then such Takeda New Technology shall thereafter be deemed excluded from the Takeda Technology hereunder. [\*\*\*].

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(c) **Payment Obligations for Takeda New Technology Allocated to Optioned Biologics, Optioned Products and Collaboration Programs.** Any royalties or other amounts that become owing to such Third Party with respect to such Takeda New Technology to the extent allocable to the Development, Manufacture or Commercialization of an Optioned Biologic or Optioned Product or the Collaboration Programs hereunder and incurred after the applicable Option Exercise Date, shall be included in calculating Allowable Expenses, as applicable, *provided* that [\*\*\*], *provided* further that if Denali has exercised the Denali Worldwide Royalty Option with respect to the applicable Collaboration Program, any such royalties or other amounts shall be paid by Takeda, subject to Takeda's right to offset such payments under Section 8.7.5(e).

(d) **Payment Obligations for Takeda New Technology that is [\*\*\*].** Any royalties or other amounts that become owing to such Third Party with respect to [\*\*\*] to the extent allocable to [\*\*\*] shall be the sole responsibility of [\*\*\*].

**7.5.3 Coordination with Third Party Agreements.** The obligations of each Party and the rights of the other Party under this Agreement, including with respect to Prosecution and Maintenance and enforcement of Patents, shall be subject to, and limited by, any agreements pursuant to which such Party acquired or licensed any particular Patents or Information or other subject matter.

## **7.6 Retention of Rights.**

**7.6.1** Except as expressly provided herein, Denali grants no other right or license, including any rights or licenses to the Denali Technology, the Regulatory Documentation, Denali's Corporate Names, or any other Patent or intellectual property rights not otherwise expressly granted herein.

**7.6.2** Except as expressly provided herein, Takeda grants no other right or license, including any rights or licenses to the Takeda Technology, the Regulatory Documentation, Takeda's Corporate Names, or any other Patent or intellectual property rights not otherwise expressly granted herein.

**7.7 Confirmatory Patent License.** Each Party shall if requested to do so by the other Party promptly enter into confirmatory license agreements in the form or substantially the form reasonably requested by such other Party for purposes of recording the licenses granted under this Agreement with the applicable patent offices as such other Party considers appropriate. Until the execution of any such confirmatory licenses, so far as may be legally possible, Denali and Takeda shall have the same rights in respect of the Denali Technology and Takeda Technology, as the case may be, and be under the same obligations to each other in all respects as if the said confirmatory licenses had been executed.

## **7.8 Exclusivity.**

**7.8.1** On a Designated Target-by-Designated Target basis during the applicable Exclusivity Period, except as permitted under this Agreement, each Party agrees for itself and its Affiliates not to: (a) clinically develop, [\*\*\*] or commercialize any product containing an antibody or other protein-based therapeutic Directed to such Designated Target with an intended therapeutic effect in the CNS Field (each a "**Competing Product**"), nor (b) authorize or assist any Third Party to do any of the foregoing; *provided* that if a Designated Target is a combination of two (2) Targets, then a Competing Product shall also include any product containing an antibody that (i) is Directed to any one (1) of such Targets with an intended therapeutic effect in the CNS Field and (ii) [\*\*\*].

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**7.8.2** Notwithstanding the provisions of Section 7.8.1, if, during the Exclusivity Period, (i) a Party or any of its Affiliates acquires rights to a Competing Product through an Acquisition, such Acquisition, and the commercialization of such Competing Product thereafter, shall not constitute a breach of Section 7.8.1 if such Party or such Affiliate, as applicable, (x) [\*\*\*] and (y) prior to [\*\*\*]; or (ii) a Party [\*\*\*]; *provided*, that, such [\*\*\*].

**ARTICLE 8  
PAYMENTS**

**8.1 Upfront Payments.**

**8.1.1 Initial Equity Investment.** No later than [\*\*\*] Business Days following the Effective Date, Takeda shall purchase Four Million Two Hundred Fourteen Thousand Five Hundred Fifty-Nine (4,214,559) shares of Denali common stock for One Hundred Ten Million Dollars (\$110,000,000) (the “**Aggregate Stock Purchase Price**”) pursuant to the terms of the Stock Purchase Agreement. For the avoidance of doubt, the Aggregate Stock Purchase Price represents a price per share of approximately Twenty-Six Dollars and Ten Cents (\$26.10), which represents [\*\*\*], plus a premium as partial consideration paid in return for those rights granted to Takeda under the Agreement.

**8.1.2 Additional Upfront Consideration.** On or promptly after the Effective Date, Denali shall submit an invoice to Takeda for the Additional Upfront Consideration. Within [\*\*\*] Business Days following the date of such invoice, in partial consideration paid in return for those rights granted to Takeda under this Agreement, Takeda shall pay to Denali a one-time payment in the amount of Forty Million Dollars (\$40,000,000) (the “**Additional Upfront Consideration**”). The Additional Upfront Consideration shall not be refundable or creditable against any future payments by Takeda to Denali under this Agreement.

**8.2 Research Program Payments.**

**8.2.1 Research Milestone Payments.**

(a) With respect to each Designated Target and subject to Section 3.2.3(f), Takeda shall pay to Denali, in accordance with Sections 8.4 and 8.8, the milestone payments set forth below following the first achievement of each corresponding research milestone event set forth below (each, a “**Research Milestone**”) with respect to the [\*\*\*] to achieve the applicable stage of development:

<u>Research Milestone Event</u>	<u>Milestone Payment</u>
1. The Initiation of activities to [***]	\$5,000,000 (subject to <u>Section 8.2.1(b)</u> )
[***]	[***]
[***]	[***]

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(b) With respect to [\*\*\*] and the achievement of Research Milestone 1, [\*\*\*] shall be payable upon the [\*\*\*] and [\*\*\*] shall be payable upon [\*\*\*].

(c) With respect to the Research Milestones for each Designated Target, if Research Milestone 2 or 3 is achieved before a milestone payment has been made with respect to a lower-numbered Research Milestone, or if a Development Milestone is achieved by an Optioned Biologic or Optioned Product directed to such Designated Target before a milestone payment has been made with respect to one or more Research Milestone for such Designated Target, then all milestone payments corresponding to such lower-numbered Research Milestones for such Designated Target shall be deemed achieved upon achievement of the subsequent Research Milestone or Development Milestone, as applicable. Notwithstanding the foregoing, with respect to a particular Research Program, if [\*\*\*], then [\*\*\*].

(d) For the avoidance of doubt, a Research Milestone may be achieved after the Option Exercise Date with respect to the applicable Collaboration Program.

(e) Each Research Milestone is payable [\*\*\*] with respect to each Designated Target, regardless of how many Research Biologics meet such milestone event, and no Research Milestone payment shall be made more than [\*\*\*] times under this Agreement. The total amount payable by Takeda to Denali under this Section 8.2.1 shall not exceed (i) Twenty-Five Million Dollars (\$25,000,000) with respect to each Designated Target and (ii) Seventy-Five Million Dollars (\$75,000,000) in the aggregate. In the event the Parties replace any Designated Target with a Replacement Designated Target, then Takeda shall not be required to make any Research Milestone Payment with respect to such Replacement Designated Target to the extent such Research Milestone Payment has already been made by Takeda for the original Designated Target. Notwithstanding the foregoing, if [\*\*\*] and, at the time of such replacement, only [\*\*\*] of the milestone payment corresponding to Research Milestone 1 has been paid pursuant to Section 8.2.1(b), then a milestone payment of [\*\*\*] shall be due upon achievement of Research Milestone 1 with respect to the applicable Replacement Designated Target (which achievement may occur prior to such replacement and the milestone shall be paid in accordance with the terms of Section 8.4); provided that if such Replacement Designated Target is [\*\*\*] will be due upon [\*\*\*].

**8.2.2 Option Exercise Fee.** On a Collaboration Program-by-Collaboration Program basis, if Takeda submits the Option Exercise Notice to Denali, Denali shall submit to Takeda an invoice for the one-time payment in the amount of Five Million Dollars (\$5,000,000) (the “**Option Exercise Fee**”). Takeda shall pay such Option Exercise Fee by the later of [\*\*\*] Days after: (i) receipt of such invoice or (ii) the Parties have received all required approvals from all applicable governmental authorities pursuant to Section 3.2.4(c).

### 8.3 Development Milestones.

**8.3.1** With respect to each Collaboration Program for which Takeda exercises its Option and each corresponding Optioned Target, Takeda shall pay to Denali, in accordance with Sections 8.4 and 8.8, the milestone payments set forth below following the first

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achievement of each of the following development and regulatory milestones (each, a “**Development Milestone**”) for the [\*\*\*] to achieve the applicable stage of development:

<b>Development Milestone Event</b>	<b>Milestone Payment</b>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

**8.3.2** For purposes of this Section 8.3:

(a) The [\*\*\*] for the purposes of Development Milestones 1, 2 and 3 in the table above may, but need not, be the same [\*\*\*].

(b) With respect to a given Optioned Target, if a [\*\*\*] is [\*\*\*], and a [\*\*\*] was not previously conducted for [\*\*\*], then a [\*\*\*] will be deemed [\*\*\*] and [\*\*\*] solely for purposes of determining payments under this Section 8.3. Similarly, if [\*\*\*], and a [\*\*\*] and/or [\*\*\*] was not [\*\*\*], then such [\*\*\*] will be deemed [\*\*\*] solely for purposes of determining payments under this Section 8.3. Any such event deemed to have been achieved, if it would have triggered a payment under Section 8.3, will trigger a payment at the time it is deemed to have occurred. For example, consider the following scenario: [\*\*\*].

**8.3.3** Upon [\*\*\*], Takeda shall pay to Denali, in accordance with Sections 8.4 and 8.8, an additional milestone payment equal to [\*\*\*], *provided* that such milestone payment shall instead be [\*\*\*] (such payment, as applicable, the “**Additional Event Payment**”) if [\*\*\*]. If at the time of [\*\*\*], the Additional Event Payment has not been paid or become payable, then upon [\*\*\*], such Additional Event Payment (with the amount thereof determined pursuant to this Section 8.3.3 at the time of [\*\*\*]) shall also become due and payable to Denali. For clarity, the Additional Event Payment will be due one time only for all Collaboration Programs.

**8.3.4** Each Development Milestone shall be due [\*\*\*] with respect to each Collaboration Program, regardless of how many Optioned Biologics and/or Optioned Products meet such milestone event, and no Development Milestone payment shall be made more than [\*\*\*] under this Agreement. The Additional Event Payment payable pursuant to Section 8.3.3 shall be due only once under this Agreement. The total amount payable by Takeda to Denali

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under this Section 8.3 shall not exceed: (i) [\*\*\*] with respect to each Collaboration Program, except for the Collaboration Program in connection with which the Additional Event Payment is triggered, in which case the total amount payable by Takeda to Denali under this Section 8.3 for such Collaboration Program only shall not exceed [\*\*\*]; and (ii) Seven Hundred Seven Million Five Hundred Thousand Dollars (\$707,500,000) in the aggregate.

**8.4 Reports and Payments for Research Milestones and Development Milestones.** With respect to each Research Milestone set out in Section 8.2.1 and each Development Milestone set out in Section 8.3, the Party who achieves such Research Milestone or Development Milestone, as applicable, (or under whose authority such Research Milestone or Development Milestone, as applicable, is achieved) shall notify the other Party in writing within [\*\*\*] Business Days after the achievement thereof. If Denali notifies Takeda of such milestone event, Denali shall include an invoice for the corresponding milestone payment with such notice. If Takeda notifies Denali of such milestone event, Denali shall promptly after receipt of such notice submit an invoice to Takeda for the corresponding milestone amount. Takeda shall pay to Denali the corresponding milestone payment set out in Section 8.2.1 or Section 8.3, as applicable, no later than [\*\*\*] days after receipt of the applicable invoice. If any Research Milestone is achieved with respect to any Research Biologic Directed to an Initial Designated Target prior to the Effective Date, then Denali shall notify Takeda of the achievement of such milestone on or promptly after the Effective Date and shall submit an invoice to Takeda for the corresponding milestone payment (or include such amount in the invoice to be submitted to Takeda by Denali pursuant to Section 8.1.2), which invoice shall become due and payable within [\*\*\*] Business Days after receipt. If any Research Milestone is achieved with respect to any Research Biologic Directed to a Replacement Designated Target prior to the approval of the initial Research Plan by the JSC for such Replacement Designated Target, then Denali shall notify Takeda of the achievement of such milestone and, promptly after such approval and notice, Denali shall submit an invoice to Takeda for the corresponding milestone payment, which invoice shall become due and payable within [\*\*\*] days after receipt. For example, if [\*\*\*] occur prior to the Effective Date or prior to the applicable approval of the initial Research Plan by the JSC, then Denali shall notify Takeda and Takeda shall pay such corresponding milestone payment in accordance with the foregoing provisions. For the avoidance of doubt, each milestone payment set forth in Section 8.2.1 and Section 8.3 shall not be refundable and shall not be creditable against future milestone payments or other amounts paid or payable by Takeda to Denali under this Agreement.

**8.5 Commercial Milestones.** With respect to each Optioned Product Directed to a particular Optioned Target, Takeda shall pay to Denali, in accordance with Section 8.8, a one-time milestone payment (each, a “Sales Milestone”) in the amount of Seventy-Five Million Dollars (\$75,000,000) the first time Annual Net Sales for such Optioned Product equal or exceed [\*\*\*]. Promptly after the achievement of such Sales Milestone, Denali shall submit an invoice to Takeda for the corresponding milestone payment. Each such Sales Milestone shall be due no later than [\*\*\*] days after receipt of the applicable invoice. Each milestone payment made under this Section 8.5 shall not be refundable or creditable against any future payments by Takeda to Denali under this Agreement.

**8.6 Cost-Profit Sharing.** On a Collaboration Program-by-Collaboration Program basis, beginning on the Option Exercise Date and until the Co-Funding End Date if Denali

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exercises the Denali Worldwide Royalty Option with respect to such Collaboration Program, Denali and Takeda shall share equally: (a) Development Costs, (b) Allowable Expense and (c) Net Revenues as follows.

#### 8.6.1 Costs.

(a) **General.** Within [\*\*\*] Business Days, unless such timing is adjusted by approval of the JSC, after the end of each calendar month, each Party will provide the other Party with a good faith estimate of the Development Costs and Allowable Expenses it incurred for each applicable Collaboration Program in such calendar month. The Finance Working Group will establish the level of detail necessary in such estimate for each Party to satisfy its internal reporting requirements. No later than [\*\*\*] Business Days prior to the end of each Calendar Quarter, unless such timing is adjusted by approval of the JSC, each Party will provide the other Party with a reasonably detailed estimate of the Development Costs and Allowable Expenses it incurred for such Collaboration Program in such Calendar Quarter, which will include the actual costs for the first two calendar months and good faith estimate for the last month of such quarter. Within [\*\*\*] Business Days after the end of each Calendar Quarter, unless such timing is adjusted by approval of the JSC, each Party will provide other Party with a report of actual Development Costs and Allowable Expenses for such Collaboration Program for such Calendar Quarter, which report will contain a detailed and itemized calculation of such costs for each Optioned Product. Notwithstanding the foregoing, the JSC may agree to have different reporting requirements for Development Costs and Allowable Expenses for any Collaboration Program. In addition to the annual approval of the relevant budgets for each Collaboration Program, prior to the end of each Calendar Year, each Party will provide the Finance Working Group with a non-binding estimate of its Development Costs and Allowable Expenses for each Collaboration Program for the [\*\*\*] year period (detailed on a Calendar Year basis) following the first Calendar Year covered by such approved budget; *provided*, that the Parties will review and discuss such estimated costs at the Finance Working Group and/or the JPT for the relevant Collaboration Program.

(b) **Expense Review.** Each Party shall have the right to review and submit any reasonable objection to the Development Costs or Allowable Expenses set forth in the other Party's report within [\*\*\*]. Any dispute as to respect to a Development Cost or Allowable Expense shall be resolved by the Finance Working Group in accordance with Section 8.6.6.

**8.6.2 Net Sales and Net Revenues.** In order to satisfy each Party's internal reporting requirements, within [\*\*\*] Business Days, unless such timing is adjusted by approval of the JSC, after the end of each calendar month, each Party will provide the other Party with a good faith estimate of Net Sales and Net Revenues for each applicable Collaboration Program for such calendar month in the countries for which it is the Commercial Lead. The Finance Working Group will establish the level of detail necessary in such estimate for each Party to satisfy its internal reporting requirements and reporting requirements pursuant to its applicable Accounting Standards. Within [\*\*\*] Business Days prior to the end of each Calendar Quarter, unless such timing is adjusted by approval of the JSC, each Party will provide the other Party with a reasonably detailed estimate of Net Sales and Net Revenues for such Calendar Quarter in the countries for which it is the selling Party, which will include the actual Net Sales and Net

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Revenues for the first [\*\*\*] calendar months and a good faith estimate for the last calendar month of such Calendar Quarter. Within [\*\*\*] days after the end of each Calendar Quarter, unless such timing is adjusted by approval of the JSC, each Party will provide the other Party with a report of Net Sales and Net Revenue for such Calendar Quarter in the countries for which it is the Commercial Lead, which report will contain a detailed and itemized calculation of Net Sales and Net Revenues for each Optioned Product in such countries during such Calendar Quarter.

**8.6.3 Reporting, Reconciliation and True-Up.** Within [\*\*\*] days after the end of each Calendar Quarter, Takeda will calculate and provide to each Party and the Finance Working Group a report of the amount each Party is responsible for with respect to all Collaboration Programs such that the Parties share equally all Development Costs and Allowable Expenses, subject to Section 8.6.1, and all Net Revenues, for each Collaboration Program for such Calendar Quarter (excluding any Collaboration Program for which Denali has exercised the Denali Worldwide Royalty Option after the Co-Funding End Date for such Collaboration Program). The Parties will make a balancing payment between the Parties in order to effect the net revenue and cost allocation set forth in this Section 8.6 within [\*\*\*] days after delivery of such report. Notwithstanding the foregoing, to the extent a Party incurs Development Costs or Allowable Expenses prior to the Option Exercise Date for a particular Collaboration Program (collectively “**Pre-Option Expenses**”), such Pre-Option Expenses shall be reconciled and true-up between the Parties as a part of the reconciliation with respect to such Collaboration Program for the first Calendar Quarter after the Option Exercise Date for such Collaboration Program (but only if Takeda exercises the Option for the applicable Collaboration Program).

**8.6.4 Certain Other Matters Relating to Cost Calculations.**

(a) On a Calendar Year basis, if the Development Costs and Allowable Expenses incurred by a Party are in excess of the applicable Development Budget and/or Commercialization Budget, such excess amounts may be included in calculating the amount of Development Costs and Allowable Expenses incurred in such Calendar Year and to be shared by the Parties only to the extent that such amounts do not exceed [\*\*\*] of the total amounts to be incurred by such Party in such Calendar Year under all Development Budgets and Commercialization Budgets, in the aggregate for such Calendar Year; *provided however* that [\*\*\*].

(b) **Allocation of FTE Costs and Out-of-Pocket Costs.** It is understood that Development Costs and Allowable Expenses shall (A) [\*\*\*], and (B) [\*\*\*]. To the extent that any activity is conducted (or an Out-of-Pocket Cost or FTE Cost is incurred) in support of both an Optioned Product and other products, services or efforts of a Party, or in support of more than one Collaboration Program, and to the extent any Out-of-Pocket Costs or FTE Costs incurred are otherwise not solely attributable to a particular Collaboration Program in the Territory, then such Out-of-Pocket Costs and FTE Costs for the applicable activity shall be included in Development Costs and Allowable Expenses only to the extent fairly and reasonably allocated between the relevant Collaboration Program and such other products, services or efforts or other Collaboration Programs, respectively, in each case in accordance with Accounting Standards. [\*\*\*].

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(c) **Treatment of Overhead; Other Matters.** The Parties acknowledge and agree that Development Costs and Allowable Expenses shall not include any allocation of overhead except [\*\*\*]. Except to the extent already included in FTE Costs, Development Costs and Allowable Expenses shall not include either Party's costs to the extent pertaining to legal, accounting, finance or alliance management activities associated with overseeing execution of and compliance with this Agreement, unless otherwise agreed by the Parties under this Agreement or otherwise in writing. Development Costs and Allowable Expenses shall also exclude any costs attributable to a breach of this Agreement by either Party.

**8.6.5 Financial Reporting Activities; Finance Working Group.** With respect to the financial reporting activities between the Parties, unless Denali has exercised the Denali Worldwide Royalty Option for all Collaboration Programs, the JSC shall establish a finance working group ("**Finance Working Group**") to coordinate the activities and reporting by the Parties as set forth in Section 8.6.1 and to assist the JSC in its responsibilities with respect to the review and resolution of financial matters. In particular, the Finance Working Group shall:

- (a) facilitate the creation of Development Budgets and Commercialization Budgets, including the annual updates thereto;
- (b) reconcile financial and accounting matters between the Parties;
- (c) initiate and execute an effective and efficient revenue and cost sharing process (cross-charges);
- (d) cooperate to ensure that any Development Budget or Commercialization Budget agreed to for a Calendar Year (or any other given period) can be interpreted for the purposes of both Parties' internal financial and audit reporting requirements, including each Party's fiscal year reporting;
- (e) monitor the budget, expense and revenue reporting requirements between the Parties related to the Collaboration Programs to ensure that each Party is able to comply with its respective internal financial and audit reporting requirements and, as appropriate, recommending to the JSC for approval, changes to the reporting requirements under this Agreement; and
- (f) undertake such other tasks with respect to the implementation and reporting for the Parties' sharing of Development Costs, Allowable Expenses and Net Revenues as the Parties mutually agree.

**8.6.6 Cost-Profit Sharing Disputes.** [\*\*\*].

**8.7 Denali Worldwide Royalty Option.**

**8.7.1 Exercise by Denali.** On a Collaboration Program-by-Collaboration Program basis, after the Option Exercise Date, Denali may, upon prior written notice to Takeda as specified in this Section 8.7.1, opt out of sharing future Development Costs, Allowable Expenses and Net Revenues with respect to all Optioned Products within the applicable Collaboration Program in the Territory and instead receive a royalty on sales of such Optioned

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Products in the Territory (a “**Denali Worldwide Royalty Option**”). Denali shall provide (a) [\*\*\*] prior written notice if Denali exercises such right [\*\*\*], and (b) [\*\*\*] prior written notice if Denali exercises such right [\*\*\*]. The date on which the applicable notice period expires is referred to in this Agreement as the “**Co-Funding End Date**”.

**8.7.2 Co-Funding Termination.** Notwithstanding anything to the contrary in this Agreement, on a Collaboration Program-by-Collaboration Program basis, if Denali is in arrears of its payment obligation with respect to Denali’s portion of those Development Costs and Allowable Expenses with respect to a particular Collaboration Program owed to Takeda in accordance with Section 8.6.3 for a given Calendar Quarter (excluding any amounts subject to an ongoing dispute resolution process under Section 8.6.6), Takeda may issue a notice terminating Denali’s rights and obligations to share Development Costs, Allowable Expenses and Net Revenues with respect to such Collaboration Program (a “**Co-Funding Termination**”), which shall be automatically effective if Denali does not pay to Takeda [\*\*\*] amounts with respect to such Collaboration Program in accordance with Section 8.6.3 (excluding any amounts subject to an ongoing dispute resolution process under Section 8.6.6), within [\*\*\*] following Denali’s receipt of such notice [\*\*\*].

**8.7.3 Applicability to the Agreement.** Except as expressly set forth otherwise in this Agreement, a Co-Funding Termination [\*\*\*] pursuant to Section 8.7.2 shall for all purposes have the same effect as Denali having exercised the Denali Worldwide Royalty Option.

**8.7.4 Effect of Denali Worldwide Royalty Option.** Following the exercise of the Denali Worldwide Royalty Option with respect to a Collaboration Program, without limiting the other terms and conditions of this Agreement applicable to such Denali Worldwide Royalty Option, and effective from and after the Co-Funding End Date or the effective date of the Co-Funding Termination pursuant to Section 8.7.2, as the case may be: (a) Denali shall not be obligated or allowed to share in Development Costs, Allowable Expenses and Net Revenues accrued after such Co-Funding End Date or effective date of the Co-Funding Termination, as applicable; (ii) Takeda shall make the applicable royalty payments to Denali as set forth in Section 8.7.5; and (iii) Takeda shall be the Development Lead, Regulatory Lead, Manufacturing Lead (subject to Section 5.2) and Commercial Lead for Optioned Products included in the applicable Collaboration Program in the entire Territory, and Denali’s right with respect to the co-commercialization of such Optioned Products under Section 6.2.4 included in the applicable Collaboration Program shall expire; provided that Denali may conduct certain Development activities as the Parties mutually agree in writing. Once exercised with respect to a particular Collaboration Program and the Optioned Products Directed to the Optioned Target of such Collaboration Program, such Denali Worldwide Royalty Option shall be irrevocable.

**8.7.5 Royalties.** If Denali exercises the Denali Worldwide Royalty Option for a Collaboration Program, Takeda shall make the following royalty payments to Denali for sales of the relevant Optioned Products in the Territory:

(a) **Base Case Denali Worldwide Royalty Option Royalties.** In the event Denali exercises the Denali Worldwide Royalty Option pursuant to Section 8.7.1 (or a Co-Funding Termination occurs) before Denali has co-funded Development Costs and Allowable Expenses for such Collaboration Program that [\*\*\*], Takeda shall pay to Denali royalties at the applicable royalty rates specified in the table below on the Net Sales of the Optioned Products included in such Collaboration Program in the Territory.

<u>Collaboration Program Annual Net Sales</u>	<u>Royalty Rate</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

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(b) **Denali [\*\*\*] Royalties** In the event Denali exercises the Denali Worldwide Royalty Option pursuant to Section 8.7.1 (or a Co-Funding Termination occurs) after Denali has co-funded Development Costs and Allowable Expenses for such Collaboration Program that [\*\*\*] in aggregate, in lieu of the royalties specified in Section 8.7.5(a), Takeda shall pay to Denali royalties at the applicable royalty rates specified in the table below on the Net Sales of the Optioned Products included in such Collaboration Program in the Territory.

<u>Collaboration Program Annual Net Sales</u>	<u>Royalty Rate</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(c) **Royalty Term.** Royalties under Section 8.7 shall be payable on Net Sales on a country-by-country basis beginning upon the First Commercial Sale of an Optioned Product in a country in the Territory until the expiration of the Royalty Term in such country (at which time sales in such country shall be excluded from all calculations of aggregate Net Sales hereunder). “**Royalty Term**” means, with respect to a country and Optioned Product, the period commencing on the First Commercial Sale of such Optioned Product in such country and ending upon the later of (i) the expiration of the last to expire Valid Claim in (A) a Denali Patent [\*\*\*] claiming [\*\*\*] of such Optioned Product [\*\*\*] or (B) a Takeda Patent (i) claiming (x) [\*\*\*] of [\*\*\*] included in the applicable Optioned Product or (y) [\*\*\*] of the applicable Optioned Product, or the Optioned Biologic included in such Optioned Product, [\*\*\*] and (ii) [\*\*\*] (ii) the expiration of all Regulatory Exclusivity for such Optioned Product, and (iii) [\*\*\*] after First Commercial Sale of such Optioned Product in such country.

(d) **Reduction For Biosimilar Entry In A Country.** On an Optioned Product-by-Optioned Product basis, the royalty rates set forth in Section 8.7.5 for Net Sales of such Optioned Product in a country of the Territory shall be reduced by [\*\*\*] during which the Biosimilar Competition Percentage in such country with respect to the applicable Optioned Product is [\*\*\*] and shall be reduced to [\*\*\*] during which the Biosimilar Competition Percentage in such country with respect to such Optioned Product is [\*\*\*].

(e) **In-License Agreements.** The Parties shall each be responsible for [\*\*\*] of any royalties related to the sale of an Optioned Product or other payments with respect to Optioned Products due under any In-License Agreement to the extent provided in Sections 7.5.1, 7.5.2, or 9.4, as applicable. At Denali’s request, Takeda shall credit Denali’s portion of any such amount owed pursuant to this Section 8.7.5(e), and which is paid by Takeda, against any royalties payable to Denali pursuant to this Section 8.7.5. Takeda shall take such credit during any Calendar Quarter for which royalties are payable hereunder; *provided*, that in no event will such credit reduce such royalties for such Calendar Quarter and a Collaboration Program by more than [\*\*\*]. Any share of Denali’s portion that remains uncredited due to the application of such floor may be carried forward to subsequent Calendar Quarters.

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(f) **Manner of Royalty Payment.** Within [\*\*\*] days following the end of each Calendar Quarter after the First Commercial Sale of an Optioned Product in the Territory (or if later the first Calendar Quarter in which royalties are payable by Takeda to Denali in accordance with this Section 8.7.5), Takeda shall provide Denali with a report containing the following information for the applicable Calendar Quarter and on an Optioned Product-by-Optioned Product basis (to the extent applicable): [\*\*\*]. Takeda shall pay all amounts due to Denali under this Section 8.7, including with respect to Net Sales by Takeda, its Affiliates and their respective Sublicensees, for such Calendar Quarter at the time of the submission of such quarterly report.

**8.8 Mode of Payment.** All payments to either Party under this Agreement shall be made from a U.S. or Japanese entity (through a banking institution located in the United States or Japan) by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice to the paying Party. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using an exchange rate equal to the daily average of the rates of exchange for the currency of the country from which the amounts are payable as reported by Bloomberg or an equivalent resource as agreed by the Parties, during the Calendar Quarter for which a payment is due.

## **8.9 Withholding Taxes.**

**8.9.1** The amounts payable pursuant to this Agreement (“**Payments**”) shall not be reduced on account of any Taxes unless required by Applicable Law. A payor shall deduct and withhold from the Payments any Taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, the Parties shall use commercially reasonable efforts to take all such acts and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty, and if a recipient is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding tax, it may deliver to the payor or the appropriate governmental authority the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the payor of its obligation to withhold tax. In such case, the payor shall apply the reduced rate of withholding, or not withhold, as the case may be, *provided* that the payor is in receipt of evidence (e.g., the recipient’s delivery of all applicable documentation), in a form reasonably satisfactory to the payor, at least [\*\*\*] week prior to the time that the Payments are due. If, in accordance with the foregoing, the payor withholds any amount, it shall pay to the recipient the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send the recipient proof of such payment within [\*\*\*] days following that payment.

**8.9.2** If a Party that owes a payment under this Agreement assigns its rights and obligations to any person as permitted in accordance with Section 16.3 and if, solely as a result of such assignment, the withholding or deduction of taxes required by Applicable Law with respect to payments owed by such assignee under this Agreement is increased, then any amount payable under this Agreement shall be increased to take into account such withheld or deducted taxes as may be necessary so that, after making all required tax withholdings and deductions (including tax withholdings and deductions on amounts payable under this Section 8.9), the payee receives an amount equal to the sum it would have received absent such assignment.

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**8.10 Indirect Taxes.** All payments are exclusive of value added taxes, sales taxes, consumption taxes and other similar taxes (the “**Indirect Taxes**”). If any Indirect Taxes are chargeable in respect of any payments, the paying Party shall pay such Indirect Taxes at the applicable rate in respect of such payments following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by the receiving Party in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes. If the Indirect Taxes originally paid or otherwise borne by the paying Party are in whole or in part subsequently determined not to have been chargeable, all reasonably necessary steps requested by the paying Party will be taken by the receiving Party to receive a refund of these undue Indirect Taxes from the applicable governmental authority or other fiscal authority and any amount of undue Indirect Taxes repaid by such authority to the receiving Party (net of any amounts incurred with respect to the receipt of such amounts) will be transferred to the paying Party within [\*\*\*] days of receipt.

**8.11 Interest on Late Payments.** If any payment or portion thereof due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon at a rate equal to [\*\*\*], plus [\*\*\*] or, if lower, the maximum rate permitted by Applicable Law, calculated on the number of days such payment is delinquent, compounded annually and computed on the basis of a three hundred sixty-five (365) day year.

**8.12 Financial Records.** Each Party shall keep complete and accurate books and records pertaining to Development Costs, Allowable Expenses and Net Revenues with respect to the Optioned Products, and Development of the Optioned Biologics or Optioned Products, including books and records of actual expenditures with respect to the budgets set forth in each Development Plan and each Commercialization Plan, in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its obligations under this Agreement. Such books and records shall be retained by such Party until the later of (a) [\*\*\*] years after the end of the period to which such books and records pertain, and (b) the expiration of the applicable tax statute of limitations (including any extensions thereof), or for such longer period as may be required by Applicable Law.

**8.13 Audit.** At the request of the other Party, each Party shall permit an independent public accounting firm of nationally recognized standing designated by the other Party and reasonably acceptable to the audited Party, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records maintained pursuant to Section 8.12 to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (a) be conducted for any Calendar Quarter more than [\*\*\*] years after the end of such quarter, (b) be conducted more than once in any [\*\*\*] period (unless a previous audit during such [\*\*\*] period revealed an underpayment with respect to such period) or (c) be repeated for any Calendar Quarter; except in each case, for cause. The accounting firm shall disclose to the auditing Party whether the reports are correct or not, and the details concerning any discrepancies sufficient for the auditing Party to understand any such discrepancies. Absent manifest error by such independent accounting firm, the determination of such independent accounting firm shall be

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binding on the Parties. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of more than the greater of [\*\*\*] or [\*\*\*] from the reported amounts for the inspected period, in which case the audited Party shall bear the cost of the audit. If such audit concludes that (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 8.11, or (ii) excess payments were made by the audited Party, the auditing Party shall, at its election, reimburse such excess payments or elect that such excess payments shall be offset against future payments due to the auditing Party under this Agreement, in either case ((i) or (ii)), within [\*\*\*] days after the date on which such audit is completed by the auditing Party.

**8.14 Confidentiality.** The receiving Party shall treat all information subject to review under this Article 8 in accordance with the confidentiality provisions of Article 11 and the Parties shall enter into a reasonably acceptable confidentiality agreement with the independent accountant obligating such accountant to retain all such financial information in confidence pursuant to such confidentiality agreement.

**8.15 No Other Compensation.** Each Party hereby agrees that the terms of this Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by one (1) Party to the other Party in connection with the transactions contemplated herein. Neither Party previously has paid or entered into any other commitment to pay, whether orally or in writing, any of the other Party's employees, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transaction contemplated herein.

## ARTICLE 9 INTELLECTUAL PROPERTY

### 9.1 Ownership of Intellectual Property.

**9.1.1 Ownership of Patents and Know-How Generated under this Agreement.** Each Party shall solely own all rights, title and interest in and to all Information and inventions that are conceived, discovered, developed or otherwise made by or on behalf of such Party or its Affiliates and Sublicensees, in conducting activities with respect to a Research Biologic, Optioned Biologic, Optioned Product or a Designated Target under this Agreement, together with all intellectual property rights therein, provided that Denali shall own [\*\*\*] (the "**Covered ATV Platform Technology**") and any claim of a Patent Covering such Information and invention shall be deemed an [\*\*\*]. Takeda hereby assigns, and agrees to assign, to Denali all right, title and interest in and to all Covered ATV Platform Technology and the same shall be deemed to be Denali's Confidential Information for all purposes under this Agreement, notwithstanding Sections 1.38, 11.1.2 and 11.1.5. Other than any Covered ATV Platform Technology, the Parties shall each own an equal, undivided interest in any and all rights, title and interest in and to all Information and inventions that are conceived, discovered, developed or otherwise made by or on behalf of both Parties or their respective Affiliates and sublicensees jointly, in conducting activities with respect to a Research Biologic, Optioned Biologic, Optioned Product or a Designated Target under this Agreement, together with all intellectual property rights therein (such Information, the "**Joint Program Know-How**") and the Patents

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claiming Joint Program Know-How, the “**Joint Program Patents**”). [\*\*\*]. Notwithstanding the foregoing, the Parties acknowledge that, [\*\*\*] under this Agreement (the “**Required Assigned Technology**”). Without limiting the foregoing, Takeda hereby assigns, and agrees to assign, to Denali such Required Assigned Technology and the same shall be deemed to be Denali’s Confidential Information for all purposes under this Agreement, notwithstanding Sections 1.38, 11.1.2 and 11.1.5.

**9.1.2 Assignment and Disclosure Obligation.** Each Party shall cause all employees who perform activities for such Party under this Agreement to be under an obligation to assign their rights in any Information and inventions resulting therefrom to such Party. For clarity, the requirements of Sections 7.4 and 16.15 shall apply to each Party’s use of Third Party Providers, Affiliates and/or Sublicensees, to perform activities for such Party under this Agreement.

**9.1.3 Ownership of Corporate Names.** Each Party shall retain all right, title and interest in and to its Corporate Names.

**9.2 Maintenance and Prosecution of Patents.** As between the Parties, with respect to Denali Patents, Takeda Patents, ATV Platform Patents, Product Patents and Joint Program Patents:

**9.2.1 Assignment of Controlling Party.**

(a) **Product Patents.** Denali shall be the Controlling Party with respect to any Product Patents worldwide. Unless agreed to by the Parties, Denali shall file the Product Patents in at least the countries and jurisdictions set forth in Schedule 9.2.1(c) and use Commercially Reasonable Efforts to [\*\*\*]. Notwithstanding Section 9.2.3, [\*\*\*].

(b) **ATV Platform Patents and Other Denali Patents.** Denali shall be Controlling Party with respect to the (i) ATV Platform Patents and (ii) other Denali Patents that are not Product Patents or Joint Program Patents, in each case, worldwide and at Denali’s sole cost and expense. Notwithstanding Sections 9.2.2 and 9.2.3, Denali’s obligations under Sections 9.2.2 and 9.2.3 with respect to ATV Platform Patents and such Denali Patents shall be [\*\*\*]. For avoidance of doubt, [\*\*\*].

(c) **Takeda Patents; and Joint Program Patents that are not ATV Platform Patents.** Takeda shall be the Controlling Party with respect to (i) [\*\*\*] (collectively, such Patents described in (i) and (ii), “**Takeda Prosecuted Patents**”), worldwide and at Takeda’s sole cost and expense. [\*\*\*].

**9.2.2 Controlling Party.** Responsibility for the Prosecution and Maintenance of the Denali Patents, Takeda Patents and Joint Program Patents shall be allocated as set out above in Section 9.2.1. The Controlling Party with respect to a Patent shall have the right, but not the obligation, through the use of outside counsel reasonably acceptable to the Non-Controlling Party, to Prosecute and Maintain such Patent worldwide, subject to the terms of this Section 9.2. The Controlling Party shall keep the Non-Controlling Party fully informed of all steps with regard to the Prosecution and Maintenance of such Patent, including by providing the Non-

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Controlling Party with a copy of material communications to and from any patent authority regarding such Patents, and by providing the Non-Controlling Party drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for the Non-Controlling Party to review and comment thereon. The Controlling Party shall consider in good faith the requests and suggestions of the Non-Controlling Party with respect to such drafts and with respect to strategies for Prosecution and Maintenance of such Patent, and implement, as appropriate, such requests and suggestions of the Non-Controlling Party. To the extent the Controlling Party does not agree with any such comments from the Non-Controlling Party, such disagreement shall be referred promptly to the Patent Working Group for resolution. If the Patent Working Group cannot reach agreement on such matter [\*\*\*], then [\*\*\*]. Notwithstanding the foregoing, the Controlling Party shall promptly inform the Non-Controlling Party of any adversarial patent office proceeding, including a request for, or filing or declaration of, any interference, or Post-Grant Proceeding relating to such a Patent. Subject to Section 9.3.2, the Parties shall thereafter consult and cooperate to determine a course of action with respect to any such proceeding and the Controlling Party shall consider in good faith all comments, requests and suggestions provided by the Non-Controlling Party.

**9.2.3 Step In Rights.** In the event that the Controlling Party decides not to Prosecute and Maintain a [\*\*\*], or any claim thereof in a country or other jurisdiction, the Controlling Party shall provide reasonable prior written notice to the Non-Controlling Party of such intention (which notice shall, in any event, be given no later than [\*\*\*] days prior to the next deadline for any action that may be taken with respect to such Patent in such country or other jurisdiction), the Non-Controlling Party shall thereupon have the option, in its sole discretion, to assume the control and direction of the Prosecution and Maintenance of such Patent at its expense in such country or other jurisdiction. Upon the Non-Controlling Party's written acceptance of such option, the Controlling Party shall reasonably cooperate with the Non-Controlling Party in such country or other jurisdiction as provided under Section 9.2.2.

**9.2.4 Patent Working Group.** The Parties shall establish a patent working group ("Patent Working Group") to the extent useful to facilitate cooperation with respect to Prosecution and Maintenance activities contemplated by this Section 9.2 and coordination between the Parties with respect to such matters.

**9.2.5 Patent Term Extension and Supplementary Protection Certificate.** The Controlling Party shall be responsible for making decisions regarding patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable. The Controlling Party shall have the responsibility of applying for any extension or supplementary protection certificate with respect to such Patents. The Controlling Party shall keep the Non-Controlling Party fully informed of its efforts to obtain such extension or supplementary protection certificate. The Non-Controlling Party shall provide prompt and reasonable assistance, as requested by the Controlling Party, including by taking such action as patent holder as is required under any Applicable Law to obtain such patent extension or supplementary protection certificate. The Controlling Party shall pay all expenses in regard to obtaining the extension or supplementary protection certificate (except to the extent any such expense constitutes an Allowable Expense).

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**9.2.6 Patent Listings.** The Commercial Lead for a particular Optioned Product in a particular country of the Territory shall have the sole right to make all patent listings of Denali Patents and Takeda Patents (including Joint Program Patents, in each case) with Regulatory Authorities for such Optioned Product in such country, provided that [\*\*\*]. Subject to the foregoing proviso, the other Party shall cooperate with the Commercial Lead's reasonable requests in connection therewith, including meeting any submission deadlines, to the extent required or permitted by Applicable Law.

**9.2.7 Prosecution and Maintenance Costs.** Except as otherwise expressly provided in this [Section 9.2](#), Out-of-Pocket Costs incurred by a Party in connection with the Prosecution and Maintenance activities undertaken by a Party pursuant to this [Section 9.2](#) shall be included in the Allowable Expense; *provided* that if Denali has exercised the Denali Worldwide Royalty Option with respect to any Collaboration Program, such Out-of-Pocket Costs related to such Collaboration Program shall be shared equally between the Parties.

### **9.3 Enforcement of Patents.**

**9.3.1 Notice.** Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement of the ATV Platform Patents, Product Patents, or other Joint Program Patents, Denali Patents or Takeda Patents by a Third Party of which such Party becomes aware based on the development, commercialization, or an application to market a product containing a Research Biologic, Optioned Biologic or any Optioned Product (each, a "Product Infringement").

#### **9.3.2 Prosecuted Infringements.**

(a) **First Right.** Prior to the exercise of the Option with respect to a Collaboration Program, Denali shall have the sole right to prosecute any Product Infringement or Post-Grant Proceeding arising in connection with the prosecution of any Product Infringement. Following exercise of the Option with respect to a Collaboration Program, the Enforcing Party shall have the first right, but not the obligation, to prosecute any Product Infringement or Post-Grant Proceeding arising in connection with the prosecution of such Product Infringement, including the defense of the validity and enforceability of any such Patent that is the subject of such Product Infringement (the "Prosecuted Infringements"). For any particular Collaboration Program in any particular territory subject to the first sentence of this [Section 9.3.2\(b\)](#), the Party that is the Commercial Lead for such Collaboration Program in such territory shall have the first right to be the Enforcing Party with respect to prosecution of all Product Infringement with respect to (i) [\*\*\*] and (ii) [\*\*\*], in each case, pertaining to an Optioned Biologic or Option Product within such Collaboration Program in such territory. Subject to [Section 9.3.2\(c\)](#), Takeda shall have the sole right to be the Enforcing Party with respect to the prosecution of all Product Infringement with respect to [\*\*\*]. Denali shall have the sole right to be the Enforcing Party with respect to the prosecution of all Product Infringement with respect to [\*\*\*], unless such [\*\*\*] is (x) a [\*\*\*] or (y) [\*\*\*].

(b) **Backup Enforcement Rights for Product Patents.** Subject to the last two sentences of [Section 9.3.2\(a\)](#) above, if the Party having the first enforcement right (but not the sole right) under [Section 9.3.2\(a\)](#) does not take commercially reasonable steps to

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prosecute a Product Infringement (i) within [\*\*\*] days following [\*\*\*], or (ii) provided such date occurs after the first such notice of the Product Infringement is provided, [\*\*\*] Business Days before [\*\*\*], whichever comes first, then the other Party may be the Enforcing Party and prosecute such Prosecuted Infringement at its own expense.

(c) **Coordination of Enforcement Rights and Non-Enforcing Party Participation Rights.** In the event the Enforcing Party prosecutes any Prosecuted Infringement, the Non-Enforcing Party, where necessary, shall furnish a power of attorney solely for such purpose or shall join in, or be named as a necessary party to, such action. The Non-Enforcing Party shall have the right to join as a party to such claim, suit, or proceeding and participate with its own counsel at its own expense; *provided* that the Enforcing Party shall retain control of the prosecution of such claim, suit, or proceeding. During the conduct of any Prosecuted Infringement by an Enforcing Party with respect to the alleged or threatened infringement of Product Patents or Joint Program Patents by an infringer, the Non-Enforcing Party agrees not to conduct a Prosecuted Infringement with respect to the same infringer other than as a necessary party to or joined in such Prosecuted Infringement prosecuted by the Enforcing Party or with the prior written consent of the Enforcing Party.

**9.3.3 Conduct of Patent Litigation Under the Biologics Price Competition and Innovation Act.** If either Party receives a copy of an application submitted to the FDA under Subsection (k) of Section 351 of the PHSA or equivalent in any other jurisdiction (a “**Biosimilar Application**”) naming an Optioned Product as a reference product or otherwise becomes aware that such a Biosimilar Application has been filed (such as in an instance described in Section 351(l)(9)(C) of the PHSA), either Party shall, within [\*\*\*] Business Days, notify the other Party so that the other Party may seek permission to view the application and related confidential information from the filer of the Biosimilar Application under Section 351(l)(1)(B)(iii) of the PHSA or equivalent in any other jurisdiction. If either Party receives any equivalent or similar certification or notice in any other jurisdiction, either Party shall, within [\*\*\*] Business Days, notify and provide the other Party with copies of such communication. Regardless of the Party that is the “reference product sponsor” for purposes of such Biosimilar Application, the Commercial Lead in a particular country in the Territory with respect to the applicable Collaboration Program shall be the Enforcing Party and the Enforcing Party shall have the sole right, but not the obligation, to initiate litigation against the filer of the Biosimilar Application, including whether or not to utilize, in whole or in part, the procedures provided in Section 351 of the PHSA or equivalent in any other jurisdiction, provided that Denali shall be the Enforcing Party with respect to any [\*\*\*] and [\*\*\*] or [\*\*\*] and Takeda shall be the Enforcing Party with respect to any [\*\*\*]. If an Enforcing Party institutes any such litigation, then the other Party shall join as a party to such claim, suit or proceeding in any country requiring it as a party.

**9.3.4 Cooperation; Settlement.** The Parties agree to cooperate fully in any infringement action pursuant to this [Section 9.3](#) and consult with the other as to the strategy for the defense of the Denali Patents, Takeda Patents, and Joint Program Patents. During any such claim, suit, or proceeding, the Enforcing Party shall: (a) provide the Non-Enforcing Party with drafts of all pleadings and other material documents filed with the court or tribunal prior to their submission, in sufficient time to allow the Non-Enforcing Party to review, consider and substantively comment thereon; (b) reasonably consider taking action to incorporate the Non-Enforcing Party’s comments on all such all pleadings and other material documents; and (c) not settle any such claim, suit, or proceeding in a manner that: (i) [\*\*\*]; or (ii) [\*\*\*].

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**9.3.5 Expenses.** Except as otherwise expressly provided in this Section 9.3, Out-of-Pocket Costs incurred by a Party in connection with a Prosecuted Infringement or otherwise in performing activities pursuant to this Section 9.3 shall be (i) included as Allowable Expenses; or (ii) otherwise borne by the Party who is the Enforcing Party if and after Denali exercises the Denali Worldwide Royalty Option.

**9.3.6 Recovery.** Except as otherwise provided in this Section 9.3.6, any recovery obtained as a result of litigation described in Section 9.3.1 or 9.3.3 (whether by way of settlement or otherwise) shall be, after first reimbursing each Party's Out-of-Pocket Costs, included in Net Sales. If Denali exercises the Denali Worldwide Royalty Option, such recoveries received with respect to the applicable Collaboration Program and any period after Denali exercised such Denali Worldwide Royalty Option shall be first applied to reimburse each Party's Out-Of-Pocket Costs and the remainder shall be shared at a rate of [\*\*\*] to Takeda and [\*\*\*] to Denali.

**9.4 Infringement Claims by Third Parties.** If the manufacture, sale, or use of an Optioned Biologic or Optioned Product in the Territory pursuant to this Agreement results in, or may result in, any claim, suit, or proceeding by a Third Party alleging patent infringement by a Party (or its Affiliates or Sublicensees), such Party shall promptly notify the other Party thereof in writing. Unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against any such claim, suit, or proceeding that names such Party as a defendant; *provided* that the other Party may participate in any such claim, suit, or proceeding with counsel of its choice. Without limitation of the foregoing, if a Party finds it necessary or desirable to join the other Party as a party to any such action, such other Party shall execute all papers and perform such acts as shall be reasonably required. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit, or proceeding. Each Party agrees to provide the other Party with copies of all pleadings filed in such action and to allow the other Party reasonable opportunity to participate in the defense of the claims. The Party who is subject to an infringement action agrees not to settle such action, or make any material admissions or assert any position in such action, in a manner that [\*\*\*]. Except as otherwise agreed by the Parties, Out-of-Pocket Costs incurred by a Party in performing activities pursuant to this Section 9.4 shall be included in Allowable Expenses, or if Denali has exercised the Denali Worldwide Royalty Option with respect to the relevant Collaboration Program, borne by Takeda subject to Takeda's right to offset [\*\*\*] of such costs against its royalty obligations to Denali.

#### **9.5 Invalidity or Unenforceability Defenses or Actions.**

**9.5.1 Notice.** Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Denali Patents, Takeda Patents or Joint Program Patents by a Third Party, in each case of which such Party becomes aware.

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**9.5.2 Product Patents and Joint Program Patents Not in Connection with a Prosecuted Infringement.** The Controlling Party with respect to the Prosecution and Maintenance of a Product Patent or Joint Program Patent (other than a Joint Program Patent that is a Takeda Prosecuted Patent), as determined in accordance with Section 9.2.1, shall have the right, but not the obligation, to defend and control the defense of the validity and enforceability of such Product Patent or Joint Program Patent that does not arise in connection with any Prosecuted Infringement. The Non-Controlling Party may participate in any such claim, suit, or proceeding with counsel of its choice at its own expense; *provided* that the Controlling Party shall retain control of the defense in such claim, suit, or proceeding. If the Controlling Party elects not to defend or control the defense of such Patents, or otherwise fails to initiate and maintain the defense of any such claim, suit or proceeding, then the Non-Controlling Party may conduct and control the defense of any such claim, suit or proceeding at its own expense.

**9.5.3 [\*\*\*] Patents and [\*\*\*] Patents.** As between the Parties, [\*\*\*] shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the (i) [\*\*\*] Patents and (ii) other [\*\*\*] Patents that are not [\*\*\*] Patents or [\*\*\*] Patents, in each case, at its own expense.

**9.5.4 [\*\*\*] Patents.** [\*\*\*] shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the [\*\*\*] Patents at its own expense.

**9.5.5 Cooperation.** Each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in this Section 9.5, including by being joined as a party plaintiff in such action or proceeding, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours, and consult with the other as to the strategy for the defense of the Denali Patents, Takeda Patents, and Joint Program Patents. In connection with any such defense or claim or counterclaim, the controlling Party shall not settle any such claim, suit, or proceeding in a manner that: (i) [\*\*\*]; or (ii) [\*\*\*]. Except as otherwise expressly provided in this Section 9.5, Out-of-Pocket Costs incurred by a Party in performing activities pursuant to this Section 9.5 shall be (a) included in as Allowable Expenses, or (b) otherwise borne by the Party who is the controlling Party if and after Denali exercises the Denali Worldwide Royalty Option, to the extent not otherwise reimbursed.

**9.5.6** Notwithstanding anything to the contrary in this Section 9.5, in the event any invalidity and/or unenforceability action is a counterclaim to or part of a declaratory judgment action in anticipation of an enforcement action, then the terms and conditions of Section 9.3 shall apply, and not Sections 9.5.2 through 9.5.4.

## **9.6 Product Trademarks.**

**9.6.1 Ownership and Prosecution of Product Trademarks.** Takeda shall own all right, title, and interest to the Product Trademarks in the Territory, and shall be responsible for the registration, prosecution, and maintenance thereof. Denali shall provide all assistance and documents reasonably requested by Takeda in support of its prosecution, registration, and maintenance of the Product Trademarks.

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**9.6.2 Enforcement of Product Trademarks.** Takeda shall have the sole right and responsibility for taking such action as Takeda, after consultation with Denali, deems necessary against a Third Party based on any alleged, threatened, or actual infringement, dilution, misappropriation, or other violation of, or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory.

**9.6.3 Third Party Claims.** Takeda shall have the sole right and responsibility for defending against any alleged, threatened, or actual claim by a Third Party that the use or registration of the Product Trademarks in the Territory infringes, dilutes, misappropriates, or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party against a Party in connection with the use of the Product Trademarks with respect to an Optioned Product in the Territory.

**9.6.4 Notice and Cooperation.** Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks in the Territory and of any actual or threatened claim that the use of the Product Trademarks in the Territory violates the rights of any Third Party. Each Party agrees to cooperate fully with the other Party with respect to any enforcement action or defense commenced pursuant to this Section 9.6.

**9.6.5 Out of Pocket Costs.** All Out-of-Pocket Costs incurred by a Party in performing activities pursuant to this Section 9.6 shall be an Allowable Expense; provided that from and after the Co-Funding End Date following Denali's exercise of the Denali Worldwide Royalty Option with respect to a Collaboration Program, each Party shall be solely responsible for all Out-of-Pocket costs it incurs pursuant to this Section 9.6.

**9.7 Inventor's Remuneration.** Each Party shall be solely responsible for any remuneration that may be due such Party's inventors under any applicable inventor remuneration laws.

## ARTICLE 10 PHARMACOVIGILANCE AND SAFETY

**10.1 Pharmacovigilance.** Within [\*\*\*] days after the Option Exercise Date for the first Collaboration Program, the Parties shall enter into an agreement to initiate a process for the exchange of safety data (including post-marketing spontaneous reports received by each Party and its Affiliates) in a mutually agreed format in order to monitor the safety of the Optioned Biologics or Optioned Products and to meet reporting requirements with any applicable Regulatory Authority (the "**Pharmacovigilance Agreement**"). Notwithstanding the foregoing, after the Option Exercise Date, in no case shall exchange of adverse events ("**AEs**") occur later than [\*\*\*] days for fatal or life threatening AEs, [\*\*\*] days for other related serious AEs, and [\*\*\*] days for non-serious AEs.

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## 10.2 Global Safety Database.

**10.2.1** Denali shall initially set up, hold, and maintain the global safety database for Optioned Biologics and Optioned Products with respect to safety data obtained in connection with each Research Program and the Early Stage Development Activities for each Collaboration Program.

**10.2.2** In connection with the commencement of Late Stage Development Activities by Takeda for a Collaboration Program and in accordance with the Transition Plan, Denali shall transfer to Takeda, in the electronic format agreed upon by the Parties at the JPT, the complete contents of the safety database maintained by Denali pursuant to Section 10.2.1 for the Optioned Biologics and Optioned Products corresponding to such Collaboration Program. Thereafter Takeda shall maintain the global safety database for such Optioned Biologics and Optioned Products. Each Party's and its Affiliates' costs incurred in connection with receiving, recording, reviewing, communicating, reporting, and responding to adverse events with respect to such Optioned Biologics and Optioned Product and in establishing and maintaining a global safety database for such Optioned Biologics and Optioned Products shall be included in the calculation of Allowable Expenses; provided that from and after the Co-Funding End Date following Denali's exercise of the Denali Worldwide Royalty Option with respect to a Collaboration Program, each Party shall be solely responsible for all such costs it incurs.

## ARTICLE 11 CONFIDENTIALITY AND NON-DISCLOSURE

**11.1 Confidentiality Obligations.** At all times during the Term and for a period of [\*\*\*] following termination or expiration of this Agreement in its entirety, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is reasonably necessary or useful for the performance of such Party's obligations, or the exercise of rights expressly granted to such Party under, this Agreement. Notwithstanding the foregoing, to the extent the receiving Party can demonstrate by documentation or other competent proof, the confidentiality and non-use obligations under this Section 11.1 with respect to any Confidential Information shall not include any information that:

**11.1.1** has been published by a Third Party or otherwise is or becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party;

**11.1.2** is in the receiving Party's possession prior to disclosure by the disclosing Party, to the extent the receiving Party has the right to use and disclose such information;

**11.1.3** is subsequently lawfully received by the receiving Party from a Third Party, to the extent the receiving Party has the right to use and disclose such information without breach of any agreement between such Third Party and the disclosing Party;

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11.1.4 is published or otherwise generally made available to Third Parties by the disclosing Party without restriction on disclosure; or

11.1.5 is independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination is in the public domain or in the possession of the receiving Party.

**11.2 Permitted Disclosures.** Each Party may disclose Confidential Information to the extent that such disclosure is:

**11.2.1** in the reasonable opinion of the receiving Party's legal counsel, required to be disclosed pursuant to law, regulation or a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental body of competent jurisdiction, (including by reason of filing with securities regulators, but subject to Section 11.4); *provided*, that the receiving Party shall, unless otherwise prohibited, first have given advanced written notice (and to the extent possible, at least [\*\*\*] Business Days' notice) to the disclosing Party and (other than with regard to disclosures to securities regulators or to comply with applicable securities law, which disclosures are covered in Section 11.4) give the disclosing Party a reasonable opportunity to take whatever action it deems necessary to protect its Confidential Information. In the event that no such protective order or other remedy is obtained, or the disclosing Party waives compliance with the terms of this Agreement, the receiving Party shall furnish only that portion of Confidential Information which the receiving Party is advised by counsel is legally required to be disclosed;

**11.2.2** made by or on behalf of the receiving Party to the Regulatory Authorities in connection with any filing, application or request for Regulatory Approval in accordance with the terms of this Agreement; *provided*, that reasonable measures shall be taken to assure confidential treatment of such Confidential Information to the extent practicable and consistent with Applicable Law;

**11.2.3** made by or on behalf of the receiving Party to a patent authority as may be reasonably necessary or useful for purposes of preparing, obtaining, defending or enforcing a Patent in accordance with the terms of this Agreement; *provided*, that reasonable measures shall be taken to assure confidential treatment of such Confidential Information, to the extent such protection is available;

**11.2.4** made to its or its Affiliates' financial and legal advisors who have a need to know such disclosing Party's Confidential Information and are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or under written agreements of confidentiality and non-use, in each case, substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 11;

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**11.2.5** made by the receiving Party or its Affiliates to potential or actual investors or acquirers as may be necessary in connection with their evaluation of such potential or actual investment or acquisition; *provided*, that such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 11:

**11.2.6** made by a Party or its Affiliates or Sublicensees to its or their advisors, consultants, clinicians, vendors, service providers, contractors, existing or prospective collaboration partners, existing or prospective licensees, existing or prospective sublicensees, or other Third Parties, in each case, to the extent necessary or useful in connection with the Development of Research Biologics, Optioned Biologics or Optioned Products, the Exploitation of the Optioned Biologics, the Optioned Products, or otherwise in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement; *provided*, that such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information of the other Party substantially similar to the obligations of confidentiality and non-use in this Article 11; or

**11.2.7** a disclosure of the terms of this Agreement, which is made only on a need-to-know basis, to Persons who are subject to obligations of confidentiality and non-use substantially similar to the obligations of confidentiality and non-use in this Article 11.

For any disclosures made by the receiving Party pursuant to Sections 11.2.4–11.2.7 shall remain responsible for any failure of the relevant Person to treat such Confidential Information as required under this Article 11. For clarity, in any case where the foregoing disclosure must be subject to obligations of confidentiality and non-use substantially similar to those under this Article 11, it is understood that [\*\*\*].

**11.3 Use of Name.** Except as expressly provided in this Agreement, neither Party shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, website, or other form of publicity, without the prior written approval of such other Party. Notwithstanding the foregoing, the restrictions imposed by this Section 11.3 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by Applicable Law (including stock exchange rules); *provided*, that such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable (and in no event less than [\*\*\*] Business Days prior to the anticipated date of disclosure unless such proposed disclosure is required under Applicable Law, or the rules of an applicable securities exchange, in each case to be made in [\*\*\*] Business Days or less) so as to provide a reasonable opportunity to comment thereon.

**11.4 Public Announcements.** The Parties have agreed upon the content of a joint press release to announce the collaboration which shall be issued substantially in the form attached hereto as Schedule 11.4 upon execution of this Agreement. Neither Party shall issue any

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other public announcement, press release, or other public disclosure regarding this Agreement or the Parties' activities hereunder without the other Party's prior written consent (which shall not be unreasonably withheld, delayed, or conditioned), except for any such disclosure regarding [\*\*\*], or any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed, or is otherwise expressly permitted in accordance with this Article 11. In the event a Party desires to make a public announcement regarding the exercise of any Option or payment of any milestone or that is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [\*\*\*] Business Days prior to the anticipated date of disclosure, unless such proposed disclosure is required under Applicable Law, or the rules of an applicable securities exchange, in each case to be made in [\*\*\*] Business Days or less) so as to provide a reasonable opportunity to comment thereon. Specifically and notwithstanding the foregoing, the Parties acknowledge that [\*\*\*]. As used in this Section 11.4, [\*\*\*]. After release of any such press release, public announcement, public disclosure or presentation by a Party in accordance with this Section 11.4, such Party may further disclose the information contained such press release, public announcement, public disclosure or presentation without the need for further notice to or review by the other Party under this Section 11.4 or otherwise.

## **11.5 Publications.**

**11.5.1** Neither Party shall publish, publicly present, or otherwise publicly disclose any materials that [\*\*\*] or pertain to [\*\*\*], except in accordance with Section 11.5.2, without the prior written consent of the other Party, not to be unreasonably withheld, delayed, or conditioned. Each Party shall submit any such proposed publication or presentation to the other Party in accordance with Section 11.5.2.

**11.5.2** Each Party shall have the right to review any paper proposed for publication by the other Party, including any oral presentation or abstract, that contains [\*\*\*] or pertains to [\*\*\*] or that includes [\*\*\*]. Before any such paper is submitted for publication or an oral presentation is made, the publishing or presenting Party shall deliver a then-current copy of the paper or materials for oral presentation to the other Party at least [\*\*\*] days prior to submitting the paper to a publisher or making such other presentation or disclosure. The other Party shall review any such paper and give its comments to the publishing Party within [\*\*\*] days of the delivery of such paper to the other Party. With respect to oral presentation materials, abstracts and the like, the other Party shall make reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to the publishing or presenting Party with appropriate comments, if any. Notwithstanding the foregoing, the publishing or presenting Party shall comply with the other Party's request to delete references to such other Party's Confidential Information in any such paper and will withhold publication of any such paper or any presentation of same for an additional [\*\*\*] days in order to permit the Parties to obtain Patent protection if either Party reasonably deems it necessary. Any publication shall include recognition of the contributions of the other Party according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate. Notwithstanding the foregoing, prior to the Option Exercise Date for a Collaboration Program, Denali shall have the sole right to [\*\*\*], provided that Takeda shall have [\*\*\*]. Notwithstanding

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the foregoing it is understood that the requirements of this Section 11.5.2 are subject to and limited by the provisions of Sections 11.2.1 and 11.4 (i.e., with respect to disclosures required by Applicable Law), and [\*\*\*]. Notwithstanding the foregoing, following a Denali Worldwide Royalty Option exercise with respect to a Collaboration Program, Takeda will have the [\*\*\*] right to publish or present [\*\*\*] or results of [\*\*\*], *provided* that Denali shall have the right to review and comment on any such publication or public presentation as provided in this Section 11.5.2. After release of any publication or presentation by a Party in accordance with this Section 11.5.2, such Party may further disclose the information contained in such publication or presentation without the need for further notice to or review by the other Party under this Section 11.5.2 or otherwise.

**11.6 Prior Confidentiality.** Any Information disclosed by a Party or its Affiliate to the other Party or its Affiliate prior to the Execution Date under that certain Confidentiality Agreement between the Parties or their respective Affiliates dated [\*\*\*] shall be deemed to have been disclosed under this Agreement, and covered by the provisions of this Article 11.

**11.7 Survival.** All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 11.1.

## ARTICLE 12 REPRESENTATIONS, WARRANTIES AND COVENANTS

**12.1 Mutual Representations and Warranties.** Denali and Takeda each represents and warrants to the other, as of the Execution Date, as follows:

**12.1.1 Organization.** It is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform its obligations under this Agreement.

**12.1.2 Authorization.** The execution and delivery of this Agreement and the performance by it of its obligations hereunder have been duly authorized by all necessary corporate action, and do not violate (a) such Party's charter documents, bylaws, or other organizational documents, (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound, (c) any requirement of any Applicable Law existing as of the Execution Date and applicable to such Party, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency in effect as of the Execution Date and applicable to such Party.

**12.1.3 Binding Agreement.** This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

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**12.1.4 No Inconsistent Obligation.** It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement.

**12.2 Additional Representations and Warranties of Denali.** Denali further represents and warrants to Takeda, as of the Execution Date (and [\*\*\*]), and covenants, as follows:

**12.2.1** All issued patents and patent applications owned by or exclusively licensed to Denali or any of its Affiliates that meet the description of (i) or (ii) of the Denali Patents definition are Controlled by Denali or such Affiliate(s). Such patents and patent applications that Denali owns, or licensed exclusively to Denali or any of its Affiliates, and to Denali's knowledge that are licensed non-exclusively to Denali or any of its Affiliates under any Existing In-Licensed Agreements, in each case that exist as of the Execution Date, are listed on Schedule 12.2.1 (the "**Existing Patents**").

**12.2.2** There are no claims, judgments, or settlements that have been brought or obtained against Denali or any of its Affiliates relating to the Existing Regulatory Documentation, the Existing Patents, or the Denali Know-How. No claim or litigation has been brought or to Denali's knowledge threatened in writing by any Person alleging, that (a) the Existing Patents are invalid or unenforceable, or (b) the Existing Regulatory Documentation, the Existing Patents, or the Denali Know-How, or the disclosing, copying, making, assigning, or licensing of the Existing Regulatory Documentation, the Existing Patents, or the Denali Know-How, or the Development or Commercialization of the Research Biologics as contemplated herein, does or will violate, infringe, misappropriate or otherwise conflict or interfere with, any Patent or other intellectual property or proprietary right of any Person.

**12.2.3** Denali has not granted to any Third Party any rights under the Patents and/or Information owned or in-licensed by Denali or any of its Affiliates for use in connection with the Designated Targets, and is entitled to grant the licenses to Takeda expressly provided herein.

**12.2.4** (a) To Denali's knowledge, Denali has the right to use all Information and Patents necessary to conduct the activities under the Research Programs for the Initial Designated Targets, and (b) the Development or Commercialization of the Research Biologics Directed to the Initial Designated Targets as contemplated herein will not conflict with any other license or agreement to which Denali or any of its Affiliates is a party.

**12.2.5** Neither Denali nor, to Denali's knowledge, any counter party is in material breach of any Product In-License Agreement or Platform In-License Agreement. Denali has not threatened to terminate, nor alleged any material breach under, any such Product In-License Agreement or Platform In-License Agreement. Denali has not received any written notice from any counter party to any Product In-License Agreement or Platform In-License Agreement threatening to terminate an In License Agreement or Platform In-License Agreement or alleging that Denali is in material breach of a Product In-License Agreement or Platform In-License Agreement. To Denali's knowledge, each Product In-License Agreement and Platform In-License Agreement is in full force and effect. Schedules 1.118 and 1.123 list all Product In-License

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Agreements and all Platform In-License Agreements in existence as of the Execution Date, and Denali has provided or made available to Takeda a true and complete copy of each such agreement to Takeda prior to the Execution Date.

**12.2.6** To Denali's knowledge, the Existing Patents are being prosecuted in the respective patent offices in the Territory in accordance with Applicable Law. To Denali's knowledge, the Existing Patents have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment.

**12.2.7** To Denali's knowledge, no Person is infringing or threatening to infringe or misappropriating or threatening to misappropriate the Existing Patents, the Denali Know-How, or the Regulatory Documentation.

**12.2.8** No written claim has been filed, or to Denali's knowledge, threatened in writing, against Denali or any of its Affiliates by any Third Party alleging that the conception, development, or reduction to practice of the Regulatory Documentation, the Existing Patents, or Denali Know-How constitute or involved the misappropriation of trade secrets or other rights or property of any Person.

**12.2.9** Denali has conducted, and to Denali's knowledge, its contractors and consultants have conducted, all Development of the Research Biologics prior to the Execution Date in accordance with Applicable Law. Denali and its Affiliates have employed (and, with respect to such tests and studies that Denali will perform, will employ) Persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of the pre-clinical and Clinical Studies with respect to the Research Biologics.

**12.2.10** Neither Denali nor any of its employees nor to its knowledge, any of the agents performing hereunder, has ever been, is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. For purposes of this provision, the following definitions shall apply:

(i) A "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or biological product application.

(ii) A "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

(iii) An "**Excluded Individual**" or "**Excluded Entity**" is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

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(iv) A “**Convicted Individual**” or “**Convicted Entity**” is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

**12.3 Additional Covenants of Denali.** Denali covenants to Takeda as follows:

**12.3.1** [\*\*\*], Denali shall: (a) [\*\*\*], (b) [\*\*\*], (c) [\*\*\*], (d) [\*\*\*], or (e) [\*\*\*].

**12.3.2** During the Term, Denali shall (a) [\*\*\*], and (b) [\*\*\*].

**12.3.3** Denali will not [\*\*\*].

**12.3.4** If, during the Term, [\*\*\*].

**12.3.5** Denali shall be responsible for [\*\*\*].

**12.4 Additional Covenants of Takeda.** Takeda covenants to Denali as follows:

**12.4.1** During the Term, Takeda shall (a) [\*\*\*], and (b) [\*\*\*].

**12.4.2** Neither Takeda nor any of its Affiliates will [\*\*\*].

**12.4.3** If, during the Term, [\*\*\*].

**12.4.4** Takeda shall be responsible for [\*\*\*].

**12.5 DISCLAIMER OF WARRANTIES.** EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

## **ARTICLE 13 INDEMNITY**

**13.1 Indemnification of Denali.** Takeda shall indemnify Denali, its Affiliates and its and their respective directors, officers, employees, and agents (the “**Denali Indemnitees**”) and defend and save each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs, and expenses (including reasonable attorneys’ fees and expenses) (collectively, “**Indemnified Losses**”) in connection with any and all suits, investigations, claims, or demands

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of Third Parties (collectively, “**Third Party Claims**”) incurred by or rendered against the Denali Indemnitees arising from or occurring as a result of:

- (a) the Development of Research Biologics by or under the authority of Takeda;
- (b) the Development, Manufacture, Commercialization or other Exploitation of Optioned Biologics and Optioned Products by or under the authority of Takeda, including any Additional Development Activities conducted by or under the authority of Takeda; or
- (c) the negligence, reckless conduct or willful misconduct on the part of Takeda or its Affiliates or their respective directors, officers, employees, and agents in performing its or their obligations under this Agreement;
- (d) a breach by Takeda of this Agreement, including any breach of a representation, warranty or covenant by Takeda made under Article 12;

except in the case of clauses (a) through (d), for those Indemnified Losses for which Denali, in whole or in part, has an obligation to indemnify Takeda pursuant to Section 13.2 hereof, as to which Indemnified Losses each Party shall indemnify the other to the extent of their respective liability for such Indemnified Losses.

**13.2 Indemnification of Takeda.** Denali shall indemnify Takeda, its Affiliates and its and their respective directors, officers, employees, and agents (the “**Takeda Indemnitees**”), and defend and save each of them harmless, from and against any and all Indemnified Losses in connection with any and all Third Party Claims incurred by or rendered against the Takeda Indemnitees arising from or occurring as a result of:

- (a) the Development of Research Biologics by or under the authority of Denali;
- (b) the Development, Manufacture, Commercialization, or other Exploitation of the Optioned Biologics and Optioned Products, and any Research Biologics for which Takeda does not exercise the Option, by or under the authority of Denali either during the Term or after the termination of this Agreement (with respect to a Terminated Biologic or Terminated Product), including any Additional Development Activities conducted by or under the authority of Denali;
- (c) the negligence, reckless conduct or willful misconduct on the part of Denali or its Affiliates or its or their respective directors, officers, employees, and agents in performing its obligations under this Agreement;
- (d) a breach by Denali of this Agreement, including any breach of a representation, warranty or covenant by Denali made under Article 12.

except, in the case of clauses (a) through (d) above for those Indemnified Losses for which Takeda, in whole or in part, has an obligation to indemnify Denali pursuant to Section 13.1 hereof, as to which Indemnified Losses each Party shall indemnify the other to the extent of their respective liability for the Indemnified Losses.

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**13.3 Certain Indemnified Losses.** Any Indemnified Losses and all Out-of-Pocket Costs incurred by a Party to conduct its indemnification obligations under [Section 13.1](#) or [13.2](#), (other than those Indemnified Losses and Out-of-Pocket Costs that result from [\*\*\*], in connection with any Third Party Claim brought against either Party resulting directly or indirectly from (a) [\*\*\*]; (b) [\*\*\*], or (c) [\*\*\*], shall be included as an Allowable Expense, except in each case (b) and (c) with respect to any Collaboration Program for which Denali has exercised the Denali Worldwide Royalty Option. If either Party learns of any Third Party Claim with respect to Indemnified Losses covered by this [Section 13.3](#), such Party shall provide the other Party with prompt written notice thereof. The Parties shall confer with respect to how to respond to such Third Party Claim and how to handle such Third Party Claim in an efficient manner. In the absence of such an agreement, each Party shall have the right to take such action as it deems appropriate.

**13.4 Notice of Claim.** All indemnification claims in respect of a Party, its Affiliates, or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the “**Indemnified Party**”). The Indemnified Party shall give the indemnifying Party prompt written notice (an “**Indemnification Claim Notice**”) of any Indemnified Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this [Article 13](#), but in no event shall the indemnifying Party be liable for any Indemnified Losses to the extent such Indemnified Losses arise from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Indemnified Loss (to the extent that the nature and amount of such Indemnified Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Indemnified Losses and Third Party Claims.

**13.5 Control of Defense.**

**13.5.1 In General.** Subject to the provisions of [Sections 9.4](#), [9.5](#), and [9.6](#), at its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [\*\*\*] days after the indemnifying Party’s receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party’s claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party which shall be reasonably acceptable to the Indemnified Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in [Section 13.5.2](#), the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified

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Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any Indemnified Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

**13.5.2 Right to Participate in Defense.** Without limiting Section 13.5.1, any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided*, that such employment shall be at the Indemnified Party's own expense unless (a) the employment thereof, and the assumption by the indemnifying Party of such expense, has been specifically authorized by the indemnifying Party in writing, (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 13.5.1 (in which case the Indemnified Party shall control the defense), or (c) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

**13.5.3 Settlement.** With respect to any Indemnified Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Indemnified Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Indemnified Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 13.5.1, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Indemnified Loss; *provided*, that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, delayed, or conditioned). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim in a manner that would have a material adverse effect on the Indemnified Party or admit wrongdoing on behalf of the Indemnified Party, without the prior written consent of the indemnifying Party. The indemnifying Party shall not be liable for any settlement, compromise or other disposition of an Indemnified Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party.

**13.5.4 Cooperation.** Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the

indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

**13.5.5 Expenses.** Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a Calendar Quarter basis in arrears by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

**13.6 Special, Indirect, and Other Losses.** EXCEPT (A) [\*\*\*], (B) FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER [\*\*\*], AND (C) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 13, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF PROFITS OR BUSINESS INTERRUPTION (TO THE EXTENT THE SAME ARE CONSEQUENTIAL DAMAGES), HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE USE OF AN OPTIONED BIOLOGIC OR OPTIONED PRODUCT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

**13.7 Insurance.** Each Party shall obtain and carry in full force and effect the minimum insurance requirements set forth herein. Such insurance (a) shall be primary insurance with respect to each Party's own participation under this Agreement, (b) shall be issued by a recognized insurer rated by A.M. Best "A-VII" (or its equivalent) or better, or an insurer pre-approved in writing by the other Party, (c) shall list the other Party as an additional named insured thereunder, and (d) shall require [\*\*\*] days' written notice to be given to the other Party prior to any cancellation or non-renewal thereof.

**13.7.1 Types and Minimum Limits.** The types of insurance and minimum limits shall be:

(a) Worker's Compensation with statutory limits in compliance with the worker's compensation laws of the state or states in which the Party has employees in the United States (excluding Puerto Rico).

(b) Employer's Liability coverage with a minimum limit of [\*\*\*] per occurrence; *provided*, that a Party has employees in the United States (excluding Puerto Rico).

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(c) General Liability Insurance with a minimum limit of [\*\*\*] per occurrence and [\*\*\*] in the aggregate. Beginning at least [\*\*\*] days prior to the initiation of a Clinical Study, General Liability Insurance shall include Clinical Trial Insurance. Beginning at least [\*\*\*] days prior to First Commercial Sale of an Optioned Product, General Liability Insurance shall also include product liability insurance of [\*\*\*].

**13.7.2 Certificates of Insurance.** Upon request by a Party, the other Party shall provide Certificates of Insurance evidencing compliance with this Section 13.7.2. The insurance policies shall be under an occurrence form, but if only a claims-made form is available to a Party, then such Party shall continue to maintain such insurance after the expiration or termination of this Agreement for the longer of (a) a period of [\*\*\*] years following termination or expiration of this Agreement in its entirety, or (b) with respect to a particular Party, last sale of an Optioned Product (or but for expiration or termination, would be considered an Optioned Product) sold under this Agreement by a Party.

**13.7.3 Self-Insurance.** Notwithstanding the foregoing, (a) Takeda may self-insure, in whole or in part, the insurance requirements described above and (b) Denali may self-insure, in whole or in part, the insurance requirements described above [\*\*\*].

## ARTICLE 14 TERM AND TERMINATION

**14.1 Term.** This Agreement shall commence on the Execution Date (subject to Section 15.1) and, unless earlier terminated as set forth below, shall continue in force and effect until (a) the expiration of the last-to-expire Option Period if Takeda has not exercised any of its Options prior to such expiration or (b) if Takeda has exercised any of its Options prior to the expiration of the applicable Option Period, for so long as an Optioned Biologic or Optioned Product Directed to an Optioned Target is being Developed or Commercialized pursuant to this Agreement (such period, the “**Term**”).

**14.2 Termination for Material Breach.** If either Party (the “**Non-Breaching Party**”) believes that the other Party (the “**Breaching Party**”) has materially breached any of its material obligations under this Agreement, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party (a “**Default Notice**”). If the Breaching Party does not dispute that it has committed a material breach of any of its material obligations under this Agreement and the Breaching Party fails to cure such breach within [\*\*\*] after receipt of the Default Notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party; *provided* that if such material breach is with respect to only a Collaboration Program (and not this Agreement in its entirety), such termination shall be limited to such Collaboration Program. If the Breaching Party disputes the Default Notice within the [\*\*\*] cure-period, the dispute shall be resolved pursuant to Section 16.6.4. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined to be in material breach of any of its material obligations under this Agreement (an “**Adverse Ruling**”) and the Breaching Party fails to complete the actions specified by the Adverse Ruling to cure such material breach within any of the remaining [\*\*\*] cure period after such ruling is issued, then the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party; *provided* that if such material breach is with respect to only a Collaboration Program (and not this Agreement in its entirety), such termination shall be limited to such Collaboration Program. Notwithstanding anything to the contrary, in the event [\*\*\*].

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**14.3 For Convenience.** Beginning [\*\*\*] after the Effective Date, Takeda may terminate this Agreement: (a) in its entirety; or (b) with respect to a particular Designated Target(s) (and the associated Collaboration Program(s)), for any or no reason, upon [\*\*\*] days prior written notice to Denali. Without limiting Takeda's obligations under [\*\*\*], beginning after the completion of Denali's Early Stage Development Activities with respect to an Optioned Product within a Collaboration Program, if at any time Takeda has not, for a period of [\*\*\*], either directly or through an Affiliate or Third Party, engaged in [\*\*\*] activities in support of [\*\*\*] of any Optioned Product within such Collaboration Program in or for a Major Market then except to the extent (i) [\*\*\*] or (ii) [\*\*\*] was (1) [\*\*\*], or (2) [\*\*\*], Denali may, at its sole discretion, provide written notice to Takeda of its intent to terminate this Agreement with respect to such Collaboration Program and, if Takeda does not commence and sustain [\*\*\*] activities in support of [\*\*\*] of any Optioned Product within such Collaboration Program within [\*\*\*] after such notice from Denali, Denali may terminate this Agreement with respect to such Collaboration Program immediately upon written notice to Takeda. For clarity, the determination of whether the activities being undertaken by or on behalf of Takeda are [\*\*\*] for the purposes of this Section 14.3 shall be based on those activities taken as a whole, in light of then-current facts and circumstances related to such Collaboration Program, and such determination shall be subject to the dispute resolution procedures in Section 16.6.4.

**14.4 Termination for Insolvency.** Either Party may terminate this Agreement in its entirety at any time during the Term by giving written notice to the other Party if the other Party files in any court or agency pursuant to any statute or regulation of any state or country a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee for the other Party or its assets, or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed with [\*\*\*] days after the filing thereof, or if the other Party makes a general assignment for the benefit of creditors.

**14.5 Termination for Patent Challenge.** Either Party may terminate this Agreement upon notice to the other Party in the event that such other Party, or any of its Affiliates or Sublicensees, or any Third Party designated by such other Party, takes any action, directly or indirectly, or knowingly provides financial or other assistance, including legal or technical advice, directly or indirectly, to any Third Party to challenge the validity, enforceability, scope, inventorship or ownership of any of such Party's Patents that are licensed to the other Party under this Agreement in any court or tribunal or any patent office in a jurisdiction, or in any arbitration proceeding, including in connection with an opposition proceeding, re-examination or post-grant proceeding, but excluding any counter-claim filed by such Party or any of its Affiliates or Sublicensees as a defense to a claim of patent infringement of the applicable Patent licensed under this Agreement, and within [\*\*\*] days after written notice thereof by such Party, such other Party does not withdraw or cause to be withdrawn such action.

**14.6 Termination for a Material Safety Event.** With respect to any Collaboration Program for which Takeda has exercised the Option, Takeda may terminate this Agreement with respect to such Collaboration Program, upon [\*\*\*] days prior written notice to Denali, if a

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Material Safety Event occurs with respect to such Collaboration Program; *provided* that the JSC unanimously agrees that a Material Safety Event has occurred as of the date of such written notice. For such purposes a “**Material Safety Event**” means an event that [\*\*\*], is reasonably likely to [\*\*\*] that (when considered in totality) is reasonably likely: (a) [\*\*\*]; and/or (b) [\*\*\*].

#### **14.7 Effects of Termination and Option Expiration.**

**14.7.1 Licenses to Intellectual Property.** In the event of any termination of this Agreement in its entirety or with respect to a Terminated Program, subject to Section 14.10 below:

(a) all rights and licenses granted by Denali under Article 7, and all obligations of Takeda with respect thereto, shall immediately terminate with respect to the Terminated Programs;

(b) all rights and licenses granted by Takeda under Article 7, and all obligations of Denali with respect thereto, shall immediately terminate with respect to the Terminated Programs;

(c) subject to the terms of this Section 14.7.1(c) and solely with respect to the Terminated Program(s):

(i) Takeda shall, and hereby does effective as of the effective date of termination, grant Denali a license, with the right to grant multiple tiers of sublicenses, under (1) Takeda Know-How reasonably necessary to Exploit the Biologics and Products Directed to the Terminated Target(s) for the Terminated Program in the forms that are being or have been Developed and/or Commercialized at the time of such termination and Takeda’s interest in any Joint Program Know-How and (2) Takeda Patents reasonably necessary to Exploit (or that otherwise Cover) the Biologics and Products Directed to such Terminated Target(s) in the forms that are being or have been Developed and/or Commercialized at the time of such termination and Takeda’s interest in any Joint Program Patents, in each case solely for the purposes of Exploiting Biologics and Products Directed to the Terminated Target(s) for such Terminated Program(s). For avoidance of doubt, [\*\*\*].

(ii) Takeda shall assign to Denali or its designee all Regulatory Approvals, Regulatory Documentation and Product Trademarks for the Terminated Products Controlled by Takeda. In each case, unless otherwise required by Applicable Law or requested by Denali, the foregoing assignment (or availability) shall be made within [\*\*\*] days after the effective date of any expiration or termination of this Agreement, and if such assignment cannot be made under Applicable Law within such period, as soon as practicable thereafter. Pending transfer of Takeda’s Regulatory Approvals and Regulatory Documentation for the Terminated Products, Takeda hereby grants to Denali (or its designee) a right of reference to all such Regulatory Approvals and Regulatory Documentation for the Terminated Product for all uses in connection with the Terminated Product. Takeda shall provide the applicable Regulatory Authority a letter confirming this right of reference at any time within [\*\*\*] days after Denali’s request and shall take such other actions and execute such other documents as Denali may reasonably request to further confirm and give effect to this right of reference.

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Notwithstanding the definition of Confidential Information, all such Regulatory Documentation and Regulatory Approvals for the Terminated Products and all Joint Program Know-How that is [\*\*\*] to the Terminated Products shall be deemed to be the Confidential Information of Denali and not Takeda.

(iii) Denali shall additionally have the right to immediately have Takeda commence the transfer of the Manufacturing Process to Denali or its designee, with such transfer to be carried out in accordance with the terms of Section 5.6 applied *mutatis mutandis*.

(iv) Takeda shall provide to Denali the Takeda Know-How (to the extent licensed under clause (i) above), Regulatory Documentation, Clinical Data and other Information pertaining to the Terminated Program (to the extent such items exist as of the date of such termination), and Denali shall have the right to use and disclose the same in connection with the Exploitation of the Terminated Program. Takeda shall have no obligation to translate any such Takeda Know-How, Regulatory Documentation, Clinical Data or other Information into English or any other language.

(d) Promptly following any such termination, at either Party's request, the Parties shall [\*\*\*]: (i) whether [\*\*\*]; (ii) if [\*\*\*]; (iii) the [\*\*\*], *provided*, that [\*\*\*]; (iv) [\*\*\*]; and (v) [\*\*\*]. In the event the Parties [\*\*\*]. It is understood that the Parties intend [\*\*\*].

(e) Denali shall be responsible for (A) making any payments (including royalties, milestones and other amounts) payable by Takeda to Third Parties under any Third Party agreements with respect to the Patents or Information that are the subject of the licenses granted to Denali under the Takeda Know-How and/or Takeda Patents in Section 14.7.1(c) by making such payments directly to Takeda and, in each instance, Denali shall make the requisite payments to Takeda and provide the necessary reporting information to Takeda in sufficient time to enable Takeda to comply with its obligations under such Third Party agreements, and (B) complying with any other obligations included in any such Third Party agreements that are applicable to the grant to Denali of such license or to the exercise of such license by Denali or any of its Affiliates or sublicensees; and Takeda shall be responsible for paying or providing to any such Third Party any payments or reports made or provided by Denali under this Section 14.7.1(e). Upon request by Denali, Takeda shall disclose to Denali a true and complete written description of the applicable payment and other obligations under such Third Party agreements, and Denali's obligation to reimburse Takeda such amounts and comply with such obligations following such request shall be limited to those payment and other obligations as so disclosed by Takeda.

(f) Denali may terminate its license pursuant to Section 14.7.1(c) under any Patent or Information with respect to a Terminated Product by so notifying Takeda in writing, in which case the terminated Patent or Information, respectively, shall be excluded from such license and Denali shall have no obligation to pay royalties (if any are due with respect to such license) or reimburse any Third Party payments (or abide by other Third Party obligations) under Section 14.7.1 with respect to such Patent or Information to the extent so excluded. For clarity, Denali agrees to indemnify the Takeda Indemnitees and defend and save each of them

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harmless, from and against any and all Indemnified Losses in connection with any and all Third Party Claims incurred or rendered against the Takeda Indemnitees arising from or occurring as a result of the Development, Manufacture, Commercialization, or other Exploitation of any Terminated Biologic or Terminated Product in accordance with Section 13.2, and any such termination by Denali shall not limit Denali's obligation to indemnify Takeda for any such Third Party Claims made by such Third Party related to the Exploitation of the Terminated Biologic or Terminated Product after the effective date of termination.

(g) For clarity, upon any termination of this Agreement in its entirety or with respect to a Terminated Program: (i) the Designated Target for such Terminated Program (the "**Terminated Target**") shall thereafter cease to be a Designated Target, such program shall cease to be a Collaboration Program, any Biologic Directed to the Terminated Target shall cease to be a Research Biologic or Optioned Biologic, as applicable (each, a "**Terminated Biologic**"), and any product containing such Terminated Biologic (each, a "**Terminated Product**") shall cease to be a Optioned Product, as applicable, in each case for all purposes of this Agreement; and, in any case (ii) all rights of Takeda, and all obligations of Denali, under this Agreement with respect to such Terminated Target, Terminated Biologics and Terminated Products shall terminate, except for those rights and obligations expressly surviving under Sections 14.7, 14.8 and 14.10. For clarity: (A) Sections 11.4 and 11.5 shall not apply to public statements or publications by or under the authority of Denali to the extent the same pertain to the Terminated Program, Terminated Biologic, Terminated Product or Terminated Target; and (C) the Joint Committees shall have no further authority or oversight with respect to the Terminated Program.

**14.8 Transition.** In the event of termination of this Agreement, whether in its entirety or with respect to a Terminated Program, the following also shall apply.

**14.8.1 Development.** In the event Takeda is conducting (or is having conducted on its behalf) any (a) on-going Clinical Studies of Optioned Biologic or Optioned Product or (b) any ongoing non-clinical studies and/or manufacturing process development activities (including, formulation studies, stability studies, scale up tests, etc.) of Optioned Biologic or Optioned Product, in each case following the date a notice of termination has been issued by Denali or Takeda, as applicable, Takeda agrees, at Denali's request (except as provided below): (i) unless such termination was made in accordance with Section 14.6, to continue for a period of [\*\*\*] after the effective date of termination ("**Development Wind-Down Period**") any such Clinical Studies, non-clinical studies or manufacturing process development activities, or any portion thereof; or (ii) to the extent so requested by Denali, (A) to promptly transition to Denali or its designee such Clinical Studies, non-clinical studies or manufacturing process development, or portions thereof as then being conducted in accordance with the Development Plan for such Terminated Program in effect immediately prior to the applicable termination date or (B) to terminate such Clinical Studies, non-clinical studies, manufacturing process development, or portions thereof (provided that such termination would not be inconsistent with Takeda's ethical obligations). Notwithstanding the foregoing, if the relevant termination is by Takeda pursuant to Section 14.2 or 14.4, Takeda shall have the right to elect whether to continue, transition to Denali (or its designee) or wind-down any such on-going Clinical Studies. [\*\*\*].

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**14.8.2 Commercialization.** Except to the extent the applicable termination was made in accordance with Section 14.6, if this Agreement is terminated after the First Commercial Sale of a Terminated Product and Takeda is the Commercial Lead with respect to the applicable Terminated Product, Takeda, its Affiliates and its Sublicensees shall continue to distribute such Terminated Product, in accordance with the terms and conditions of this Agreement, in each country for which Regulatory Approval therefor has been obtained, until [\*\*\*] after the effective date of termination (the “**Commercialization Wind-down Period**”); *provided* that Takeda, its Affiliates and its Sublicensees shall cease such activities, or any portion thereof, in a given country upon [\*\*\*] days’ notice by Denali requesting that such activities (or portion thereof) be ceased. Notwithstanding any other provision of this Agreement, during the Commercialization Wind-down Period, Takeda’s and its Affiliates’ and Sublicensees’ rights with respect to Terminated Products shall be non-exclusive and, without limiting the foregoing, Denali shall have the right to engage one or more other distributor(s) and/or licensee(s) of the Terminated Product in all or part of the Territory. Any Terminated Product sold or disposed of by Takeda, its Affiliates or its Sublicensees in the Territory during the Commercialization Wind-down Period shall be subject to applicable payment obligations under Article 8. Unless [\*\*\*], any Terminated Product sold or disposed of by Denali, its Affiliates or its Sublicensees (but not, for clarity any sales during such period by Takeda, its Affiliates, or Sublicensees) in the Territory during the Commercialization Wind-down Period shall be subject to applicable payment obligations to Takeda under Section 14.7.1. Within [\*\*\*] days of expiration of the Commercialization Wind-down Period, Takeda shall notify Denali of any quantity of Terminated Product remaining in Takeda’s inventory and Denali shall have the option, upon notice to Takeda, to repurchase any such quantities of the Terminated Product from Takeda at a price equal to [\*\*\*] of such quantities (to the extent [\*\*\*]).

**14.8.3 Supply Obligations.** Upon Denali’s request, to the extent that Takeda is the Manufacturing Lead for the Terminated Program prior to the termination of this Agreement, Takeda shall either (a) assign to Denali Takeda’s agreement(s) with its Third Party Provider for the Terminated Biologics, Terminated Products and placebo, or alternatively, use reasonable efforts to facilitate Denali’s entering into a direct supply agreement with such Third Party Provider of the Terminated Biologics, Terminated Products and placebo on comparable terms to those between Takeda and such Third Party Provider (in each case assuming Takeda is then obtaining supply of Terminated Biologics, Terminated Products or placebo from a Third Party Provider) and (b) except to the extent the applicable termination was made in accordance with Section 14.6 (Termination for a Material Safety Event), to the extent Takeda or its Affiliate is producing its own supply of the Terminated Product, Terminated Biologic or placebo, use Commercially Reasonable Efforts to [\*\*\*], until the date on which Denali notifies Takeda in writing that Denali has secured an alternative manufacturer for the Terminated Biologics and/or Terminated Products, but in no event more for than [\*\*\*] after the effective date of any expiration or termination of this Agreement. In the case of (b), Denali shall pay to Takeda a transfer price for the materials supplied equal to [\*\*\*] for Terminated Products delivered within the first [\*\*\*] after the effective date of termination, and, as the case may be, [\*\*\*] for Terminated Products delivered thereafter; *provided, however*, in the event the applicable termination was made for Denali’s breach or insolvency, the transfer price for materials supplied shall equal [\*\*\*] beginning on the effective date of the termination.

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**14.8.4 Cooperation.** Without limiting the foregoing, each Party shall use Commercially Reasonable Efforts to [\*\*\*]. If Takeda has entered into contracts that solely pertain to a Terminated Program with Third Parties (including contract manufacturers or vendors) whose services are reasonably necessary for Denali to assume responsibility for the Terminated Program, then Takeda shall, to the extent reasonably possible and requested in writing by Denali, assign all of such Third Party contracts to Denali.

**14.8.5 Grant of Rights.** Without limiting the foregoing, Denali shall grant to Takeda, its Affiliates or its Sublicensees (as the case may be) any licenses or rights of reference to any Denali Technology, Regulatory Approvals and Regulatory Documentation, Clinical Data, Information, Product Trademarks and Denali's Corporate Name reasonably necessary for Takeda, its Affiliates or its Sublicensees to fulfill the obligations set forth in this Section 14.8.

**14.9 Remedies.** Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to a Terminated Program) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

**14.10 Accrued Rights; Surviving Obligations.** Termination or expiration of this Agreement (either in its entirety or with respect to one (1) or more country(ies) or other jurisdiction(s)) for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Sections [\*\*\*] of this Agreement shall survive the termination or expiration of this Agreement for any reason. If this Agreement is terminated with respect to a Terminated Program but not in its entirety, then following such termination, the foregoing provisions of this Agreement shall remain in effect with respect to the Terminated Program (to the extent such provisions would survive and apply in the event this Agreement expires or is terminated in its entirety), and all provisions not surviving in accordance with the foregoing shall terminate upon termination of this Agreement with respect to the Terminated Program and be of no further force and effect (and, for purposes of clarity, all provisions of this Agreement shall remain in effect with respect to any Collaboration Program that is not the Terminated Program).

**14.11 Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement are intended to be, and shall otherwise be deemed to be, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code for purposes of Section 365(n) of the United States Bankruptcy Code (the "**Bankruptcy Code**") or any analogous provisions in any other country or jurisdiction. The Parties agree that the licensee of such intellectual property under this Agreement shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, or any analogous provisions in any other country or jurisdiction. If a bankruptcy proceeding is commenced by or against either Party under the Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the non-debtor Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed hereunder, and embodiments of such intellectual property, which, if not already in the non-debtor Party's possession, shall be delivered to the non-debtor Party within [\*\*\*] Business Days of such request; *provided*, that the debtor Party is excused from its obligation to deliver such intellectual property to the extent the debtor Party continues to perform all of its obligations under this Agreement and this Agreement has not been rejected pursuant to the Bankruptcy Code or any analogous provision in any other country or jurisdiction.

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**ARTICLE 15**  
**HSR COMPLIANCE**

**15.1 HSR Act Compliance.** Notwithstanding anything to the contrary in this Agreement, this Agreement is binding upon the Parties as of the Execution Date to the extent permitted by the HSR Act, but the provisions of Article 2–Article 9 (other than Section 9.1) shall not take effect until the Effective Date. As used herein, the “**HSR Clearance Date**” means such time as: (a) the Parties shall have complied with all applicable requirements of the HSR Act; (b) the waiting period under the HSR Act shall have expired or been terminated early; (c) no judicial or administrative proceeding opposing consummation of all or any part of this Agreement shall be pending; (d) no injunction (whether temporary, preliminary or permanent) prohibiting consummation of the transactions contemplated by this Agreement or any material portion hereof shall be in effect; and (e) no requirements or conditions shall have been formally requested or imposed by the DOJ or FTC in connection therewith that are not reasonably and mutually satisfactory to the Parties (collectively, the “**HSR Conditions**”). In the event that the HSR Conditions are not met within [\*\*\*], then either Party may terminate this Agreement upon notice, in which case, notwithstanding any provisions that are stated to survive under Section 14.10, all provisions of this Agreement shall terminate and be of no force or effect whatsoever, except only that any liability of either Party for failing to comply this Section 15.1 shall survive.

**15.2 HSR Filing.** Both Parties shall promptly file following the Execution Date (and in any event, within [\*\*\*] Business Days after the Execution Date) their respective pre-merger notification and report forms with the United States Federal Trade Commission (“**FTC**”) and the United States Department of Justice (“**DOJ**”) pursuant to the HSR Act, which forms shall specifically request early termination of the initial HSR Act waiting period.

**15.3 Cooperation.**

**15.3.1** The Parties shall use diligent efforts to promptly obtain clearance required under the HSR Act for the consummation of this Agreement and the transactions contemplated hereby and shall keep each other apprised of the status of any communications with, and any inquiries or requests for additional information from, the FTC and the DOJ and shall comply promptly with any such inquiry or request; *provided, however*, that neither Party shall be required to consent to the divestiture, sale, license or other disposition or holding separate of any of its or its Affiliates’ assets or to consent to any other structural or conduct remedy, and each Party and its Affiliates shall have no obligation to contest, administratively or in court, any ruling, order or other action of the FTC or DOJ or any Third Party respecting the transactions contemplated by this Agreement.

**15.3.2** The Parties shall instruct their respective counsel to cooperate with each other and use Commercially Reasonable Efforts to [\*\*\*]. In the context of this Section 15.3.2, diligent efforts and cooperation include counsel’s undertaking: (i) to keep each other appropriately informed of communications received from and submitted to personnel of the

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reviewing antitrust authority; and (ii) to confer with each other regarding appropriate contacts with and response to personnel of the FTC or DOJ. Takeda shall be responsible for the HSR Act filings fees and each Party shall be responsible for the costs and expenses of its own legal and other advice in relating to the HSR Act filing.

## ARTICLE 16 MISCELLANEOUS

**16.1 Force Majeure.** Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement) (such event, a “**Force Majeure Event**”). The non-performing Party shall notify the other Party of such force majeure within [\*\*\*] days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use diligent efforts to remedy its inability to perform.

**16.2 Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

### **16.3 Acquisition, Change in Control, Assignment.**

**16.3.1** Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate (except as expressly permitted under this Agreement), pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided*, that (a) either Party may make such an assignment without the other Party’s consent to (i) [\*\*\*], (ii) [\*\*\*]; or (iii) [\*\*\*] and (b) Denali may [\*\*\*]. With respect to an assignment to [\*\*\*], the assigning Party shall [\*\*\*]. Any attempted assignment or delegation in violation of this Section 16.3 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Denali or Takeda, as the case may be. The permitted assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement. Without limiting

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the foregoing, the grant of rights set forth in this Agreement shall be binding upon any successor or permitted assignee of a Party, and the obligations of the other Party, including the payment obligations, shall run in favor of any such successor or permitted assignee of such Party's benefits under this Agreement.

**16.3.2** The rights to Information, materials and intellectual property: (a) Controlled by a Third Party permitted assignee of a Party, which Information, materials and intellectual property were Controlled by such assignee immediately prior to such assignment; or (b) Controlled by an Affiliate of a Party who becomes an Affiliate through any Change in Control of or Acquisition by such Party, in each case (a) and (b) prior to such assignment or transfer, as applicable, shall be automatically excluded from the rights licensed or granted to the other Party under this Agreement, so long as such Information, materials and intellectual property are not utilized by such Third Party or Affiliate in connection with the Development, Manufacture or Commercialization of a Research Biologic, Optioned Biologic or Optioned Product that incorporates any non-public Takeda Technology or Denali Technology.

**16.4 Severability.** If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

### **16.5 Governing Law, Jurisdiction and Service.**

**16.5.1 Governing Law.** This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of [\*\*\*], United States, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; *provided*, that all questions concerning (a) determination of whether Information and inventions are conceived, discovered, developed, or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States and (b) the construction or effect of Patents shall be determined in accordance with the laws of the country or other jurisdiction in which the particular Patent has been filed or granted, as the case may be. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

**16.5.2 Service.** Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 16.7 shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement in any such court.

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**16.6 Dispute Resolution.** Except for disputes resolved by the procedures set forth in [Section 2.3.6](#) or [16.10](#) or for which either Party has final decision-making authority as provided in [Section 2.3.6](#), if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “**Dispute**”), it shall be resolved pursuant to this [Section 16.6](#).

**16.6.1 General.** Any Dispute shall first be referred to the senior executive officers of the Parties, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the senior executive officers shall be conclusive and binding on the Parties. If the senior executive officers are not able to agree on the resolution of any such issue within [\*\*\*] days (or such other period of time as mutually agreed by the senior executive officers) after such issue was first referred to them, then, except as otherwise set forth in [Section 16.6.2](#) or [16.6.4](#), either Party may, by written notice to the other Party, elect to initiate a proceeding pursuant to the procedures set forth in [Section 16.6.4](#) for purposes of having the matter settled.

**16.6.2 Intellectual Property Disputes.** In the event that a Dispute arises with respect the validity, scope, enforceability, inventorship or ownership of any Patent, Trademark or other intellectual property rights, and such Dispute cannot be resolved in accordance with [Section 16.6.1](#), unless otherwise agreed by the Parties in writing, such Dispute shall not be submitted to an ADR proceeding in accordance with [Section 16.6.4](#) and instead, either Party may initiate litigation in a court of competent jurisdiction, notwithstanding [Section 16.5](#), in any country or other jurisdiction in which such rights apply.

**16.6.3 Jurisdiction.** Each of the Parties hereby submits to the jurisdiction [\*\*\*] in any proceeding arising out of or relating to this Agreement, agrees not to commence any suit, action or proceeding relating thereto except in such court, and waives, to the fullest extent permitted by law, the right to move to dismiss or transfer any action brought in such court on the basis of any objection to personal jurisdiction, venue or inconvenient jurisdiction. Any rights to trial by jury with respect to any suit, action, proceeding or claim (whether based upon contract, tort or otherwise), directly or indirectly, arising out of or relating to this Agreement hereunder are expressly and irrevocably waived by each of the Parties.

**16.6.4 Expert Arbitration.** Any dispute expressly stated in this Agreement to be resolved pursuant to this [Section 16.6.4](#) shall take place pursuant to the procedures described in [Schedule 16.6.4](#).

**16.6.5 Interim Relief.** Notwithstanding anything herein to the contrary, nothing in this [Section 16.6](#) shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, if necessary to protect the interests of such Party. This [Section 16.6.5](#) shall be specifically enforceable.

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\*\*\* Certain information in this agreement has been omitted and filed separately with the Securities and Exchange Commission. [\*\*\*] indicates that text has been omitted and is the subject of a confidential treatment request.

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## 16.7 Notices.

**16.7.1 Notice Requirements.** Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if (a) delivered by hand, (b) sent by facsimile transmission (with complete transmission confirmed), or (c) by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 16.7.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 16.7.1. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile or electronic mail (with complete transmission confirmed) or on the [\*\*\*] Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile or electronic mail shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 16.7.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

### 16.7.2 Address for Notice.

If to Takeda, to:

Takeda Pharmaceutical Company Limited  
1-1, Doshomachi 4-chome  
Chuo-ku, Osaka 540-8645  
Japan  
Attention: Legal Department  
Facsimile:

with a copy to:

Takeda Pharmaceuticals  
1 Takeda Parkway  
Deerfield, IL 60015  
Attention: General Counsel  
Facsimile:

with a further copy (which shall not constitute notice) to:

Cooley LLP  
3175 Hanover Street  
Palo Alto, CA 94304-1130  
Attention:  
E-mail:

If to Denali, to:

Denali Therapeutics, Inc.  
151 Oyster Point Blvd  
South San Francisco, CA 94080  
Attention:  
Email:

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with a copy (which shall not constitute notice) to:

Wilson Sonsini Goodrich and Rosati P.C.  
12235 El Camino Real, Suite 200  
San Diego, California 92130  
Attention:  
Facsimile:

**16.8 Entire Agreement; Amendments.** This Agreement, together with the Schedules attached hereto, and the Stock Purchase Agreement, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby (including that certain Confidentiality Agreement between the Parties or their respective Affiliates dated [\*\*\*]). Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement or the Stock Purchase Agreement. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

**16.9 English Language.** This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

**16.10 Equitable Relief.** Each Party acknowledges and agrees that the restrictions set forth in [Section 7.8](#), [Article 9](#) and [Article 11](#) are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Section or Articles may result in irreparable injury to such other Party for which there may be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent and specific performance. Nothing in this [Section 16.10](#) is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

**16.11 Waiver and Non-Exclusion of Remedies.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

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**16.12 No Benefit to Third Parties.** Except as provided in Article 13, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

**16.13 Further Assurance.** Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

**16.14 Relationship of the Parties.** It is expressly agreed that Denali, on the one hand, and Takeda, on the other hand, shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture, or agency, including for all tax purposes; *provided, however*, [\*\*\*] (and any disputes related thereto shall be resolved pursuant to Section 16.6.4 of this Agreement). Neither Denali, on the one hand, nor Takeda, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

**16.15 Performance by Affiliates And Sublicensees.** Each Party may use one (1) or more of its Affiliates and/or (sub)licensees to exercise its rights and/or perform its obligations and duties hereunder (including by licensing rights hereunder where such rights are held in the name of any such Affiliate). In such event: (a) [\*\*\*]; (b) [\*\*\*], and (d) [\*\*\*].

**16.16 Counterparts; Facsimile Execution.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

**16.17 References.** Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

**16.18 Construction.** Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way

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define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including,” “include,” or “includes” as used herein shall mean “including, but not limited to,” and shall not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

*[SIGNATURE PAGE FOLLOWS.]*

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THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Execution Date.

**Denali Therapeutics Inc.**

**Takeda Pharmaceutical Company Limited**

By: /s/ Ryan J. Watts  
Name: Ryan J. Watts  
Title: CEO

By: /s/ Fumihiko Sato  
Name: Fumihiko Sato  
Title: Head of Portfolio Strategic Relations

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[SIGNATURE PAGE TO OPTION AND COLLABORATION AGREEMENT]

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**Schedule 11.4**

**Press Release  
[ATTACHED]**

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### **Takeda and Denali Therapeutics Collaborate to Develop and Commercialize Therapies for Neurodegenerative Diseases**

*Collaboration includes three named programs for the treatment of Alzheimer's disease and other neurodegenerative diseases, utilizing Denali's Antibody Transport Vehicle (ATV) technology to enhance blood-brain barrier (BBB) penetration.*

**Osaka, Japan and South San Francisco, CA, January 5, 2018** – Takeda Pharmaceutical Company Limited (TSE: 4502) and Denali Therapeutics (NASDAQ: DNLI) today announced that they have entered into a strategic option and collaboration agreement to develop and commercialize up to three specified therapeutic product candidates for neurodegenerative diseases. Each program is directed to a genetically validated target for neurodegenerative disorders, including Alzheimer's disease and other indications, and incorporates Denali's ATV platform for increased exposure of biotherapeutic products in the brain.

"This partnership further exemplifies Takeda's continued commitment to developing genetically validated therapies for neurodegenerative diseases through an enhanced portfolio comprised of new modalities," said Emiliangelo Ratti, Head of the Neuroscience Therapy Area at Takeda. "We are excited to partner with the Denali team, whose innovative technology is uniquely poised to deliver the next generation of antibody therapeutics for patients."

"We are impressed with Takeda's commitment to developing treatments for difficult to treat neurodegenerative diseases and look forward to partnering with them to bring medicines to patients," said Denali CEO Ryan Watts, Ph.D. "Takeda has a great track record of partnering with biotech firms in addition to unique development expertise and a strong global commercial presence."

#### **Terms of Collaboration**

Under the terms of the agreement, Takeda will make an initial payment to Denali of \$150 million through a combination of cash upfront payments and the purchase of Denali equity. In addition, Denali is eligible to receive development and commercial milestone payments, including \$90 million in preclinical milestones and opt-in payments.

Denali will be responsible for all development activities and costs prior to IND filing for each of the three programs. Takeda has the option to co-develop and co-commercialize each of the three programs. If Takeda exercises the option, the parties will then jointly conduct clinical development and share all costs equally. Denali will lead early clinical development activities and Takeda will lead late stage clinical development activities. Takeda and Denali will jointly commercialize products in the United States and China, and Takeda will have exclusive commercialization rights in all other markets. The parties will share global profits equally. The agreement will become effective when the requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976 have been satisfied.

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### **About Takeda Pharmaceutical Company**

Takeda Pharmaceutical Company Limited (TSE: 4502) is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its R&D efforts on oncology, gastroenterology and neuroscience therapeutic areas plus vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology and gastroenterology, as well as Takeda's presence in emerging markets, are currently fueling the growth of Takeda. Approximately 30,000 Takeda employees are committed to improving quality of life for patients, working with Takeda's partners in health care in more than 70 countries. For more information, visit <https://www.takeda.com/newsroom/>.

Additional information about Takeda is available through its corporate website, [www.takeda.com](http://www.takeda.com), and additional information about Takeda Oncology, the brand for the global oncology business unit of Takeda Pharmaceutical Company Limited, is available through its website, [www.takedaoncology.com](http://www.takedaoncology.com).

### **About Denali Therapeutics**

Denali is a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases. Denali is based in South San Francisco. For additional information, please visit [www.denalitherapeutics.com](http://www.denalitherapeutics.com).

### **Cautionary Note Regarding Forward Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, the potential benefits of the collaboration; plans to conduct clinical development activities and commercialize products; the expectation as to when the agreement will become effective; and other information relating to the transaction between Takeda and Denali. Actual results are subject to risks and uncertainties and may differ materially from those indicated by these forward-looking statements as a result of these risks and uncertainties, including but not limited to: the risk that the agreement may not become effective in a timely manner or at all; risks related to obtaining the requisite regulatory approvals; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the agreement (including without limitation the failure to timely obtain requisite regulatory approvals); risks related to the effect of the announcement of the transaction on Denali's business relationships, operating results and business generally; and other risks, including those described in Denali's Prospectus filed with the SEC on December 8, 2017. The forward-looking statements in this press release are based on information available to Denali as of the date hereof. Denali and Takeda disclaim any obligation to update any forward-looking statements, except as required by law.



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**Takeda Contact:**

Kelly Schlemm, +1-617-551-8865  
kelly.schlemm@takeda.com

**Denali Therapeutics Contact:**

Morgan Wamers, +1-202-295-0124  
mwamers@gpg.com

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**CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Ryan J. Watts, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report on Form 10-K of Denali Therapeutics Inc.; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: July 13, 2018

/s/ Ryan J. Watts

Ryan J. Watts, Ph.D.

President and Chief Executive Officer

**CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Steve E. Krognes, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report on Form 10-K of Denali Therapeutics Inc.; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: July 13, 2018

/s/ Steve E. Krognes

Steve E. Krognes  
Chief Financial Officer and Treasurer