Denali Therapeutics Reports Third Quarter 2018 Financial Results and Business Highlights and Announces the Appointment of Jennifer Cook to Board of Directors

November 8, 2018

SOUTH SAN FRANCISCO, Nov. 08, 2018 (GLOBE NEWSWIRE) -- Denali Therapeutics Inc. (NASDAQ: DNLI), a biopharmaceutical company developing a broad portfolio of product candidates for neurodegenerative diseases, today reported financial results for the third quarter ended September 30, 2018, provided business highlights and announced the appointment of Jennifer Cook to the Board of Directors.

“The recent clinical progress with our LRRK2 inhibitor and RIPK1 inhibitor programs are important milestones towards our goal of developing medicines for patients suffering from neurodegenerative diseases,” said Ryan Watts, Ph.D., CEO. “Furthermore, we are very excited to partner with Sanofi and expand our RIPK1 program into new indications.”

Third Quarter 2018 and Recent Business Highlights

- **Presented Phase 1 data and commenced recruitment for Phase 1b clinical trial for DNL201** – On October 25, 2018 detailed preclinical and clinical data from the DNL201 Phase 1 clinical trial in healthy volunteers were presented at the Michael J. Fox Foundation Parkinson'sDisease Therapeutic Conference. The results met all endpoints and support testing DNL201 in patients. Patient recruitment has commenced for the DNL201 Phase 1b clinical trial in Parkinson’s disease patients with and without the LRRK2 mutation, with the first patient expected to be dosed in late 2018.

- **Completed dosing in DNL747 Phase 1 clinical trial** – In October 2018, dosing was completed in the DNL747 Phase 1 clinical trial in healthy volunteers. The data from this trial will be presented at the Denali 2018 R&D Day on December 10, 2018.

- **Entered into a broad RIPK1 Collaboration Agreement with Sanofi** – On October 29, 2018, Denali entered into a Collaboration and License Agreement with Genzyme Corporation, a wholly owned subsidiary of Sanofi S.A., to develop and commercialize therapeutic products to treat neurological and systemic inflammatory diseases by targeting RIPK1. Denali will receive an upfront fee of $125 million and contingent milestone payments that could exceed $1 billion. For products intended to treat neurological diseases, Denali and Sanofi will share development costs and commercial profits and losses in the United States and China, while Denali will receive a royalty from Sanofi for other territories. For products intended to treat systemic inflammatory diseases, Sanofi will pay all development costs and Denali will receive a royalty worldwide. The transaction is expected to close in the coming months in accordance with customary regulatory approvals.

- **Appointed Jennifer Cook to the Board of Directors** – On November 6, 2018 Jennifer Cook joined the Board of Directors as an independent director. Ms. Cook is the Chief Executive Officer of GRAIL. Previously, she was at Roche Pharmaceuticals and Genentech, where she held a number of senior management positions during a 25-year tenure, covering the full lifecycle of product development and commercialization. Ms. Cook holds a BA in Human Biology and an MS in Biology from Stanford University, as well as an MBA from the Haas School of Business at University of California, Berkeley.

Third Quarter 2018 Financial Results

For the three months ended September 30, 2018, Denali reported a net loss of $35.4 million compared with a net loss of $21.8 million for the three months ended September 30, 2017.

Collaboration revenue was $1.2 million for the three months ended September 30, 2018, with no collaboration revenue recognized for the three months ended September 30, 2017. The increase was due to revenue recognized under the Option and Collaboration Agreement with Takeda Pharmaceutical Company Limited, which was entered into in January 2018.

Total research and development expenses were $30.3 million for the three months ended September 30, 2018, including non-cash stock-based compensation of $2.9 million, compared to $18.5 million for the three months ended September 30, 2017, including non-cash stock-based compensation of $0.7 million. The increase in total research and development expenses of $11.8 million was primarily attributable to an increase in personnel-related expenses, including non-cash stock-based compensation, driven primarily by higher headcount and new options granted at higher exercise prices subsequent to the Company's initial public offering. Further, there was an increase in other external research and development expenses, reflecting Denali's growing and maturing pipeline, increased LRRK2 program expenses due to increased costs associated with Phase 1 clinical trials in healthy volunteers with DNL201 and DNL151, and an increase in other research and development expenses primarily due to rent expense associated with the new headquarters lease and an increase in lab consumable expenses.

General and administrative expenses were $8.8 million for the three months ended September 30, 2018, including non-cash

stock-based compensation of $2.6 million, compared to $3.8 million for the three months ended September 30, 2017, including non-cash stock-based compensation of $0.4 million. The increase in total general and administrative expenses of $5.0 million was primarily attributable to an increase in personnel-related expenses, including non-cash stock-based compensation, driven primarily by higher headcount and new options granted at higher exercise prices subsequent to the Company's initial public offering, and an increase in legal and professional service expenses required to support Denali's ongoing operations as a public company.

Cash, cash equivalents, and marketable securities were $517.1 million as of September 30, 2018, compared to $467.0 million as of December 31, 2017. The increase of $50.1 million was primarily attributable to $155.0 million in cash received related to the Option and the Collaboration Agreement and Stock Purchase Agreement with Takeda, both entered into in January 2018, partially offset by operating and investing cash payments.

About Denali Therapeutics

Denali is a biopharmaceutical company developing a broad portfolio of product candidates for neurodegenerative diseases. Denali pursues new treatments by rigorously assessing genetically validated targets, engineering delivery across the blood-brain barrier and guiding development with biomarker monitoring to demonstrate target engagement and select patients. Denali is based in South San Francisco. For additional information, please visit 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 with Sanofi; the expectation as to when such transaction will close; expectations regarding clinical development activities; plans for Sanofi and Denali to collaborate on global clinical development; and statements made by Denali's Chief Executive Officer.

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, risks related to: the risk that the Sanofi transaction may not close 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 collaboration 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; Denali's early stages of clinical drug development; Denali's ability to complete the development and, if approved, commercialization of its product candidates; Denali's ability to conduct or complete clinical trials on expected timelines; implementation of Denali's strategic plans for its business, product candidates and BBB platform technology; and other risks, including those described in Denali's Annual Report on Form 10-K filed with the SEC on March 19, 2018, Denali's Quarterly Report on Form 10-Q filed with the SEC on November 8, 2018 and Denali's future reports to be filed with the SEC. The forward-looking statements in this press release are based on information available to Denali as of the date hereof. Denali disclaims any obligation to update any forward-looking statements, except as required by law.

Denali Therapeutics Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenue	$ 1,195	$ —	$ 3,484	$ —
Operating expenses:				
Research and development	30,321	18,515	103,274	55,989
General and administrative	8,838	3,773	21,304	10,611
Total operating expenses	39,159	22,288	124,578	66,600
Loss from operations	(37,964)	(22,288)	(121,094)	(66,600)
Interest and other income, net	2,593	444	7,321	1,302
Net loss	$ (35,371)	$ (21,844)	$ (113,773)	$ (65,298)
Net loss per share, basic and diluted	$ (0.38)	$ (2.14)	$ (1.24)	$ (6.77)
Weighted average number of shares outstanding, basic and diluted	93,665,231	10,231,036	92,056,812	9,643,686

Denali Therapeutics Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 43,651	$ 218,375
Short-term marketable securities	331,307	187,851
Prepaid expenses and other current assets	8,445	3,381
Total current assets	383,403	409,607
Long-term marketable securities	142,173	60,750
Property and equipment, net	16,245	14,923
Other non-current assets	2,654	1,441
Total assets	$ 544,475	$ 486,721
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,354	$ 2,716
Accrued liabilities	7,393	5,364
Accrued compensation	4,847	5,166
Contract liability	12,658	—
Deferred rent	3,227	855
Other current liabilities	138	63
Total current liabilities	31,617	14,164
Contract liability, less current portion	44,452	—
Deferred rent, less current portion	7,103	6,294
Other non-current liabilities	124	467
Total liabilities	83,296	20,925
Total stockholders' equity	461,179	465,796
Total liabilities and stockholders’ equity	$ 544,475	$ 486,721

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Source: Denali Therapeutics Inc.