Denali Therapeutics and Royalty Pharma Announce $275 Million Royalty Funding Agreement

December 4, 2025

SOUTH SAN FRANCISCO, Calif. and NEW YORK, Dec. 04, 2025 (GLOBE NEWSWIRE) -- Denali Therapeutics Inc. (Nasdaq: DNLI) and Royalty Pharma plc (Nasdaq: RPRX) today announced a $275 million synthetic royalty funding agreement based on future net sales of tividenofusp alfa.

Tividenofusp alfa is Denali's lead investigational TransportVehicle ™-enabled enzyme replacement therapy for the treatment of mucopolysaccharidosis type II (MPS II, or Hunter syndrome). A Biologics License Application (BLA) for accelerated approval of tividenofusp alfa is under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target date of April 5, 2026.

"We are pleased to partner with Royalty Pharma, whose investment recognizes the value and potential of tividenofusp alfa for the Hunter community and supports our ability more broadly to realize the promise of the TransportVehicle platform," said Ryan Watts, Ph.D., Chief Executive Officer of Denali Therapeutics. "With these additional funds, we are well positioned to advance our development programs as we prepare for the launch of tividenofusp alfa, unlocking broad opportunities across serious diseases."

"We are delighted to partner with Denali and acquire a royalty on tividenofusp alfa, an innovative therapy that addresses a significant unmet need in the cognitive and physical manifestations of Hunter syndrome," said Pablo Legorreta, Chief Executive Officer and Chairman of the Board of Royalty Pharma. "Denali's technology platform delivers therapeutics across the blood-brain barrier and is a promising new approach to brain diseases. We are thrilled to establish a relationship with Denali and believe tividenofusp alfa is a potential practice-changing therapy that could transform the lives of patients with Hunter syndrome."

Transaction Terms

The transaction is subject to various closing conditions, including Denali achieving U.S. FDA accelerated approval of tividenofusp alfa. At the closing, Royalty Pharma will make an initial payment of $200 million and Royalty Pharma will be obligated to make an additional payment of $75 million upon achieving European Medicines Agency (EMA) approval of tividenofusp alfa by December 31, 2029. In exchange, Royalty Pharma will receive a 9.25% royalty on worldwide net sales of tividenofusp alfa from Denali. The royalty payments to Royalty Pharma will cease upon reaching a multiple of 3.0x, or 2.5x if achieved by the first quarter of 2039.

Advisors

Gibson Dunn acted as legal advisor to Denali. Goodwin Procter and Maiwald acted as legal advisors to Royalty Pharma.

About Denali Therapeutics

Denali Therapeutics Inc. is a biotechnology company pioneering a new class of biotherapeutics designed to cross the blood-brain barrier using its proprietary TransportVehicle ™ platform. With a clinically validated delivery platform and a growing portfolio of therapeutic candidates across all stages of development, Denali is advancing toward its goal of delivering effective medicines to transform the lives of people living with neurodegenerative, lysosomal storage and other serious diseases. For more information, please visit www.denalitherapeutics.com.

About Royalty Pharma

Founded in 1996, Royalty Pharma is the largest buyer of biopharmaceutical royalties and a leading funder of innovation across the biopharmaceutical industry, collaborating with innovators from academic institutions, research hospitals and non-profits through small and mid-cap biotechnology companies to leading global pharmaceutical companies. Royalty Pharma has assembled a portfolio of royalties which entitles it to payments based directly on the top-line sales of many of the industry's leading therapies. Royalty Pharma funds innovation in the biopharmaceutical industry both directly and indirectly – directly when it partners with companies to co-fund late-stage clinical trials and new product launches in exchange for future royalties, and indirectly when it acquires existing royalties from the original innovators. Royalty Pharma's current portfolio includes royalties on more than 35 commercial products, including Vertex's Trikafta and Alyftrek, GSK's Trelegy, Roche's Evrysdi, Johnson & Johnson's Tremfya, Biogen's Tysabri and Spinraza, Servier's Voranigo, AbbVie and Johnson & Johnson's Imbruvica, Astellas and Pfizer's Xtandi, Pfizer's Nurtec ODT, and Gilead's Trodelvy, and 18 development-stage product candidates.

Denali Therapeutics 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, plans, timelines and expectations related to tividenofusp alfa and Denali's TransportVehicle platform; expectations regarding the collaboration with Royalty Pharma, including financial aspects of the royalty financing agreement; the potential benefits and results of the royalty

financing agreement; expectations regarding achieving accelerated approval from the FDA; and plans to conduct development and commercialization activities.

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 of the occurrence of any event, change or other circumstance that could give rise to the termination of the agreement with Royalty Pharma; the impact of adverse economic conditions, tariffs, and inflation on Denali's business and operations; Denali's transition to a late-stage clinical drug development company; Denali's and its partners' ability to complete the development and, if approved, commercialization of its product candidates; Denali's reliance on third parties for the manufacture and supply of its product candidates; Denali's dependence on successful development of its blood-brain barrier platform technology; Denali's and its partners' ability to conduct or complete clinical trials on expected timelines; the risk of significant adverse events, toxicities, or other undesirable side effects; the uncertainty that product candidates will receive regulatory approval necessary to be commercialized; developments relating to Denali's competitors and its industry, including competing product candidates and therapies; Denali's ability to obtain, maintain or protect intellectual property rights related to its product candidates; implementation of Denali's strategic plans for its business, product candidates and blood-brain barrier platform technology; Denali's ability to obtain additional capital to finance its operations, as needed; Denali's ability to accurately forecast future financial results in the current environment; general economic and market conditions; and other risks and uncertainties, including those described in Denali's most recent Annual Report on Form 10-K and most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on February 27, 2025 and November 6, 2025, 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.

Royalty Pharma Forward-Looking Statements

The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this document unless stated otherwise, and neither the delivery of this document at any time, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof. This document contains statements that constitute "forward-looking statements" as that term is defined in the United States Private Securities Litigation Reform Act of 1995, including statements that express the company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results, in contrast with statements that reflect historical facts. Examples include discussion of Royalty Pharma's strategies, financing plans, growth opportunities, market growth, and plans for capital deployment. In some cases, you can identify such forward-looking statements by terminology such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "target," "forecast," "guidance," "goal," "predicts," "project," "potential" or "continue," the negative of these terms or similar expressions. Forward-looking statements are based on management's current beliefs and assumptions and on information currently available to the company. However, these forward-looking statements are not a guarantee of Royalty Pharma's performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks, uncertainties and other variable circumstances, and other factors. Such risks and uncertainties may cause the statements to be inaccurate and readers are cautioned not to place undue reliance on such statements. Many of these risks are outside of Royalty Pharma's control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this document are made only as of the date hereof. Royalty Pharma does not undertake, and specifically declines, any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments, except as required by law. For further information, please reference Royalty Pharma's reports and documents filed with the U.S. Securities and Exchange Commission ("SEC") by visiting EDGAR on the SEC's website at www.sec.gov.

Royalty Pharma Investor Relations and Communications

+1 (212) 883-6637
ir@royaltypharma.com

Denali Investor Contact
Laura Hansen, Ph.D.
hansen@dnli.com

Denali Media Contact
Erin Patton
epatton@dnli.com

Denali Therapeutics Inc.