Denali Therapeutics Announces Closing of Collaboration and Share Purchase Agreements with Biogen

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SOUTH SAN FRANCISCO, Calif., Oct. 07, 2020 (GLOBE NEWSWIRE) -- Denali Therapeutics Inc. (NASDAQ: DNLI), a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier (BBB) for neurodegenerative diseases, today announced the signing of a Definitive LRRK2 Collaboration and License Agreement and a Right of First Negotiation, Option and License Agreement with Biogen, in connection with its previously announced binding provisional collaboration and license agreement for neurodegenerative diseases with Biogen, and the closing of the related common stock purchase agreement.

In connection with the signing of the agreements with Biogen, Denali will receive a $560 million upfront payment. In addition, on September 22, 2020, in a private placement transaction, Biogen made an equity investment of $465 million in Denali through the purchase of 13,310,243 newly issued shares of Denali common stock at approximately $34.94 per share in connection with its previously announced stock purchase agreement.

Under the terms of the Definitive LRRK2 Collaboration and License Agreement, the companies will co-develop Denali's small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease, and will co-commercialize Denali's LRRK2 products in the United States and China, with shared responsibility for worldwide development costs (60 percent Biogen; 40 percent Denali), as well as profits and losses for commercialization in the United States (50 percent Biogen; 50 percent Denali) and China (60 percent Biogen; 40 percent Denali). Outside the United States and China, Biogen will be responsible for commercialization and will pay Denali tiered royalties. Should the LRRK2 program achieve certain development and commercial milestones, Denali will be eligible to receive up to $1.125 billion in potential milestone payments.

Mutations in LRRK2 can cause Parkinson's disease. LRRK2 is a regulator of lysosomal function, which is impaired in Parkinson's disease and may contribute to neurodegeneration. As previously announced, Denali's small molecule inhibitor of LRRK2, DNL151, has been selected to progress into late-stage clinical studies, which are expected to commence in 2021.

Under the terms of the Right of First Negotiation, Option and License Agreement with Biogen, Biogen has exclusive option rights to two programs for neurodegenerative diseases using Denali's BBB-crossing transport vehicle (TV) technology platform, including for amyloid beta, plus right of first negotiation for two additional unnamed TV platform programs should Denali decide to seek a collaboration for such programs. These rights are limited to certain modalities and indications and are also exercisable during a limited time period. Denali's proprietary TV technology is designed to effectively deliver large therapeutic molecules such as antibodies, enzymes, proteins and oligonucleotides across the BBB after intravenous administration.

The closing of the common stock purchase agreement and the definitive collaboration agreements were subject to the satisfaction of customary closing conditions, including the expiration of the waiting period under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976. Additional details regarding the financial terms can be found in Denali's Form 8-K filed with the Securities and Exchange Commission on October 7, 2020.

About Denali's LRRK2 DNL151 Program

DNL151 is a small molecule inhibitor of LRRK2 invented at Denali which has completed dosing of 162 healthy volunteers in an ongoing Phase 1 clinical study and completed dosing in 25 Parkinson's patients in a Phase 1b clinical study. Denali is currently completing further dose escalation cohorts in an expanded Phase 1 and an additional cohort in the Phase 1b study to define the full therapeutic window of the molecule. Based on the clinical data to date that has been generated in Europe, DNL151 appears to have an acceptable safety and tolerability profile and has met desired target engagement goals. An Investigational New Drug application for DNL151 was cleared by the U.S. Food and Drug Administration in July 2020 and enables expansion of Denali clinical trials for DNL151 globally.

About Denali Therapeutics

Denali Therapeutics is a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier (BBB) for neurodegenerative diseases. Denali pursues new treatments by rigorously assessing genetically validated targets, engineering delivery across the BBB and guiding development through biomarkers that demonstrate target and pathway engagement. 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, plans, timelines and

expectations related to DNL151 and other LRRK2 inhibitor molecules, Denali's TV technology platform and TV programs; LRRK2 inhibitors as modifying therapy for Parkinson's disease; the ability of the TV technology to effectively deliver large therapeutic molecules across the BBB; expectations regarding the collaboration with Biogen, including financial aspects of the collaboration; the potential benefits and results of the transaction with Biogen; expectations regarding the commencement of clinical trials; expectations regarding ongoing clinical trials; 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: any and all risks to Denali's business and operations caused directly or indirectly by the evolving COVID-19 pandemic; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the agreements with Biogen; risks related to the effect of the announcement of the transaction on Denali's business relationships, operating results, stock price and business generally; Denali's early stages of clinical drug development; Denali's and its partners' ability to complete the development and, if approved, commercialization of its product candidates; Denali's and its partners' ability to enroll patients in clinical trials; Denali's reliance on third parties for the manufacture and supply of its product candidates for clinical trials; Denali's dependence on successful development of its BBB platform technology and whether the platform technology effectively delivers large therapeutic molecules across the BBB; Denali's and its partners' ability to conduct or complete clinical trials on expected timelines; the risk that preclinical profiles and results of early clinical trials of Denali's product candidates, such as DNL151, may not translate in later clinical trials; the risk that DNL151 and Denali's other LRRK2 inhibitors may not sufficiently modify Parkinson's disease; the uncertainty that product candidates will receive regulatory approval necessary to be commercialized; Denali's ability to continue to create a pipeline of product candidates or develop commercially successful products; 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 BBB 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, most recent Quarterly Report on Form 10-Q 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.

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