Biogen and Denali to Collaborate on LRRK2 Program for Parkinson's Disease and Certain TV Platform-Enabled Programs for Neurodegenerative Diseases

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- *Biogen to receive license to co-develop and co-commercialize Denali's small molecule LRRK2 inhibitor program, expanding pipeline of potential therapies in Parkinson's disease and other movement disorders*
- *Biogen to receive exclusive option rights to two programs for neurodegenerative diseases utilizing Denali's blood-brain barrier crossing TV technology platform, including for amyloid beta, plus right of first negotiation for two additional unnamed TV platform programs*
- *Denali to receive a $560 million upfront payment, a $465 million equity investment and potential milestone payments, profit sharing and royalties*

CAMBRIDGE, Mass. and SOUTH SAN FRANCISCO, Calif., Aug. 06, 2020 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) and Denali Therapeutics Inc. (Nasdaq: DNLI) today announced that they have signed a binding agreement to co-develop and co-commercialize Denali's small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease. Biogen will also receive rights to opt into two programs and a right of first negotiation for two additional programs, in each case for neurodegenerative diseases leveraging Denali's Transport Vehicle (TV) technology platform to cross the blood-brain barrier (BBB).

"Our collaboration with Denali represents an opportunity to advance the development of a potential first-in-class oral therapy that may slow the progression of Parkinson's disease," said Michel Vounatsos, Biogen's Chief Executive Officer. "Denali's LRRK2 program is highly complementary to our existing Parkinson's disease pipeline and its successful development would enhance Biogen's portfolio of medicines for treating serious neurological and neurodegenerative diseases. We look forward to leveraging our neurology capabilities and infrastructure with Denali's scientific expertise to accelerate advancement of this program."

"We are very excited to collaborate with Biogen, a company with an impressive history in inventing and developing medicines for neurological diseases," said Ryan Watts, Ph.D., Denali's Chief Executive Officer. "This collaboration will allow us to accelerate the development of our LRRK2 program and gives us the resources to build a fully integrated company with the goal of bringing transformative medicines to patients suffering from neurodegenerative diseases."

Under the agreement, Biogen will collaborate with Denali to co-develop and co-commercialize Denali's small molecule inhibitors of LRRK2 for Parkinson's disease. Biogen and Denali will co-commercialize the LRRK2 product in the U.S. and China, and Biogen will commercialize in all other markets. DNL151 has been selected to progress into late stage clinical studies expected to commence in 2021.

Mutations in the LRRK2 gene can cause Parkinson's disease. LRRK2 is a regulator of lysosomal function, which is impaired in Parkinson's disease and may contribute to neurodegeneration. Inhibition of LRRK2 activity may slow the progression of Parkinson's disease in patients with and without known genetic risks based on restoration of lysosomal function. People who have Parkinson's disease experience numerous symptoms, including tremors, slow movement, muscle stiffness and impaired balance. As these symptoms become progressively worse, patients have difficulty walking, talking or completing other simple tasks. Parkinson's disease is the second most common neurodegenerative disease with significant unmet medical needs due to the absence of approved therapies that may slow disease progression.

In addition to the LRRK2 program, Biogen will also receive an exclusive option to license two preclinical programs from Denali's TV platform, which aims to improve brain uptake of biotherapeutics, including its Antibody Transport Vehicle (ATV): Abeta program (ATV enabled anti-amyloid beta program) and a second program utilizing its TV technology. Further, Biogen will have right of first negotiation on two additional TV-enabled therapeutics, currently at a preclinical stage, should Denali decide to seek a collaboration for such programs. Denali's TV platform is a proprietary technology designed to effectively deliver large therapeutic molecules such as antibodies, enzymes, proteins and oligonucleotides across the BBB after intravenous administration.

Terms of the Collaboration

Under the terms of the agreement, Biogen will make an upfront payment to Denali of $560 million and make a $465 million equity investment in Denali from the purchase of 13.3 million newly issued shares of Denali common stock at approximately $34.94 per share, representing 11.2 percent of Denali's pro-forma outstanding stock.

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.

In the LRRK2 collaboration, Biogen and Denali will share responsibility and costs for global development (60 percent Biogen; 40 percent Denali), and will share responsibility and costs as well as profits and losses for commercialization in the U.S. (50 percent Biogen; 50 percent Denali) and China (60 percent Biogen; 40 percent Denali). Outside the U.S. and China, Biogen will be responsible for commercialization and pay Denali tiered royalties.

Closing of the collaboration is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976 in the U.S., and other customary closing conditions.

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 Biogen

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, immunology, neurocognitive disorders, acute neurology and pain.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

About Denali Therapeutics

Denali Therapeutics is a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the BBB for neurodegenerative diseases. Denali Therapeutics 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 Therapeutics is based in South San Francisco. For additional information, please visit www.denalitherapeutics.com.

Biogen Safe Harbor

This press release contains forward-looking statements, made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements relating to the potential benefits and results that may be achieved through Biogen's proposed collaboration with Denali; the anticipated completion of the proposed transaction; the potential benefits, safety and efficacy of DNL151 and other LRRK2 inhibitor molecules; the clinical development program for DNL151 and other LRRK2 inhibitor molecules; the potential benefits of Denali's TV technology platform and TV programs including its ATV: anti-amyloid beta program; the treatment of Parkinson's disease; the potential of Biogen's commercial business and pipeline programs; Biogen's strategy and plans; the potential treatment of neurological and neurodegenerative diseases; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation: risks that the proposed transaction will be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed transaction will not be satisfied; uncertainty as to whether the anticipated benefits of the proposed collaboration can be achieved; risks of unexpected hurdles, costs or delays; uncertainty of success in the development and potential commercialization of DNL151 and other undisclosed neurological targets, which may be impacted by, among other things, unexpected concerns that may arise from additional data or analysis, the occurrence of adverse safety events, failure to obtain regulatory approvals in certain jurisdictions, failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risks factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this press release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

Denali 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 including its ATV: anti-amyloid beta program; 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 proposed transaction with Biogen, including all financial aspects of the collaboration and equity investment; the potential benefits and results of the proposed transaction with Biogen; the anticipated completion of the transaction; plans to conduct clinical development activities and commercialize products; and statements made by Denali's CEO and Biogen's CEO.

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 risks that the proposed transaction with Biogen may not be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed transaction will not be satisfied, including the finalization of a definitive collaboration agreement; risks related to obtaining the requisite regulatory approvals, including those required under antitrust laws; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the agreements with Biogen (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, 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 of Denali's product candidates, such as DNL151, may not translate in clinical trials and that such product candidates 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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