Denali Therapeutics to Present Interim Data from Phase 1/2 Study of ETV:IDS (DNL310) for the Potential Treatment of Hunter Syndrome at MPS 2021

July 15, 2021

Management to host webinar for analysts and investors on July 25th

SOUTH SAN FRANCISCO, Calif., July 15, 2021 (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 its participation at MPS 2021, the 16th Annual International Symposium of MPS and Related Diseases, a research conference dedicated to the exchange of knowledge on mucopolysaccharidoses and related syndromes, taking place virtually July 23-25, 2021. Details related to Denali's oral presentation at MPS 2021 and a webinar hosted by Denali management following the presentation are provided below.

Oral Presentation at MPS 2021

Session Title: Late Breaking News / Oral Communications
Presentation Title: Interim 24-Week Results of Cohort A in a Ph I/II Study of Intravenous DNL310 (brain-penetrant enzyme replacement therapy) in MPS II
Date: Sunday, July 25th
Session Start Time: 16:05 p.m. CEST / 10:05 a.m. EDT / 7:05 a.m. PDT

Denali's presentation is the fifth presentation during the session and is slated to start at approximately 17:05 p.m. CEST / 11:05 a.m. EDT / 8:05 a.m. PDT.

Denali Webinar for Analysts and Investors

Following the presentation, Denali will host a webinar for analysts and investors to present the interim data from the Phase 1/2 study of DNL310. The webinar will begin at approximately 11:30 a.m. EDT / 8:30 a.m. PDT on Sunday, July 25, 2021, and will be available on Denali's corporate website on the Events page under the Investor section at https://www.denalitherapeutics.com/investors/events. An archived replay of the webinar will be available for at least 30 days following the event. Preregistration for the webinar can be accessed here.

Families interested in learning more about Denali's efforts related to the discovery and development of therapeutics for the potential treatment of Hunter syndrome are invited to visit EngageHunter.com, the Denali Hunter syndrome community engagement website.

About DNL310 and Hunter Syndrome (MPS II)

Hunter syndrome (MPS II) is a rare neurodegenerative lysosomal storage disorder caused by a mutation in the gene that encodes for the enzyme iduronate-2-sulfatase (IDS). The resultant reduction or loss of IDS enzyme activity leads to accumulation of glycosaminoglycans, which causes lysosomal dysfunction and neurodegeneration as well as progressive damage to multiple organs including bone, cartilage, heart and lung. Current standard of care enzyme replacement treatment does not address neuronopathic manifestations of the disease as it does not sufficiently cross the blood-brain barrier (BBB). DNL310 is a fusion protein composed of IDS fused to Denali's proprietary Enzyme Transport Vehicle (ETV), which is engineered to cross the BBB via receptor-mediated transcytosis into the brain. Denali previously announced human biomarker proof-of-concept for its Transport Vehicle (TV) technology from Cohort A (n=5) of an ongoing Phase I/2 study of DNL310 in patients with Hunter syndrome. The study is currently enrolling Cohort B, and a Cohort C is planned to further explore clinical endpoints. More information about the ongoing Phase 1/2 study of DNL310 in patients with Hunter syndrome can be found on ClinicalTrials.gov by following this link.

About the EngageHunter.com Website
EngageHunter.com — the Denali Hunter syndrome (MPS II) community engagement website — is an online destination for emerging information or Denali's scientific advances in Hunter syndrome research and Denali's clinical trials. Visitors who register on the Engage Hunter website will receive updates on Denali's research and future Denali investigational studies.

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, statements regarding Denali's plans, timelines and expectations related to DNL310, the DNL310 ongoing Phase 1/2 study, and planned future studies, Denali's TV technology platform, and the therapeutic potential of DNL310 and Denali's TV platform. 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: Denali's early stages of clinical drug development; Denali's and its partners' ability to complete the development and, if approved, commercialization of DNL310; Denali's and its partners' ability to enroll patients in its ongoing and future clinical trials; Denali's reliance on third parties for the manufacture and supply of its product candidates for clinical trials; the potential for clinical trial results of DNL310 to differ from preclinical, preliminary or expected results, the risk that Denali will be able to continue dose escalation in the Phase 1/2 study, whether DNL310 will cause any serious adverse events, whether DNL310 will impact downstream biomarkers of neurodegeneration, and that DNL310 may not receive regulatory approval as a treatment of Hunter syndrome necessary to

be commercialized. In light of these risks, uncertainties and assumptions, the forward-looking statements in this press release are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Information regarding additional risks and uncertainties may be found in Denali's Annual and Quarterly Reports filed on Forms 10-K and 10-Q filed with the Securities and Exchange Commission (SEC) on February 26, 2021, and May 5, 2021, respectively, and Denali's future reports to be filed with the SEC. Denali does not undertake any obligation to update or revise any forward-looking statements, to conform these statements to actual results or to make changes in Denali's expectations, except as required by law.

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