Denali Therapeutics Provides Pipeline and Business Update in Response to the COVID-19 Pandemic

April 2, 2020 8:30 PM PDT

SOUTH SAN FRANCISCO, Calif., April 02, 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 provided an update on the expected pipeline and business impact from the COVID-19 pandemic.

"In these unprecedented times, our resolve to defeat degeneration is undiminished and our top priority is to ensure the health and safety of our employees, community, partners and clinical trial participants," said Ryan Watts, Ph.D., CEO. "We are very pleased with our productivity under the circumstances and we continue to generate and analyze new data across our pipeline. We are, however, experiencing enrollment delays in some of our clinical stage programs, and consequently we are actively working to maintain clinical operations to minimize any disruption."

Clinical trials and business update

- **LRRK2 program for Parkinson's disease:** the DNL201 Phase 1b trial is completed and positive results were recently presented. For the ongoing DNL151 Phase 1 and Phase 1b trials, enrollment of additional healthy volunteers and patients at higher doses has been paused due to the COVID-19 pandemic. Denali is analyzing available data from these trials and is on track to select either DNL201 or DNL151 by mid-2020 to progress into Phase 2/3 trials.

- **ETV:IDS program for Hunter Syndrome:** Denali continues to collect data from patients enrolled in the ongoing observational biomarker study. However, recruitment of additional patients has been paused due to the COVID-19 pandemic. The DNL310 Phase 1/2 trial is on track to commence in Q2 2020.

- **RIPK1 program for Alzheimer's disease and ALS:** the DNL747 Phase 1b trials are fully enrolled and have completed dosing for the primary analysis. In addition, Denali continues to collect data from the ongoing Phase 1b open-label extension study in ALS. Analysis of data from these trials is underway and Denali is on track to decide on next steps with DNL747 by mid-2020 together with its partner Sanofi.

- **EIF2B program for ALS:** the DNL343 Phase 1 trial in healthy volunteers is ongoing and dosing is completed for a portion of the study. Enrollment of additional subjects has been paused due to the COVID-19 pandemic and this could lead to a delay in the completion of the study.

Denali has drug supplies to complete ongoing trials as well as additional drug substance supplies expected to be sufficient to support planned clinical trials well into 2021. Denali currently does not expect delays to its clinical trials due to manufacturing or supply-chain issues.

Due to the evolving pandemic, the current operating environment is fluid and unpredictable. Considerable uncertainty remains in the ultimate impact on Denali's clinical trials and business. Denali is continuously assessing and adapting its working practices and business operations to ensure compliance with official guidance and orders related to the pandemic, and is working proactively with its partners and other stakeholders in an effort to mitigate and minimize any negative impact to its research, clinical programs and other business operations.

Financial update

Denali completed a common stock offering on January 31, 2020 raising approximately $207 million in gross proceeds. With cash and investments of approximately $614 million (unaudited) at the end of February 2020, Denali's business operations are expected to be funded at least through 2022.

About Denali

Denali Therapeutics is a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier 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 http://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 DNL201, DNL151, DNL310, DNL747 and DNL343; expectations regarding the sufficiency of the Company's drug and drug substance supplies; expectations regarding manufacturing and the supply chain; Denali's efforts to ensure compliance with official guidance and orders and to address the impact of COVID-19 on its research, clinical programs and other business operations; expectations regarding the sufficiency of Denali's cash and investments to fund Denali's business operations at least through 2022; 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 to Denali's business and operations, including its clinical trials, caused directly or indirectly by the evolving COVID-19 pandemic; whether Denali's efforts to mitigate and minimize any negative impact to its research, clinical programs and other business operations will be effective or sufficient; 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 enroll patients in its ongoing and future clinical trials; Denali's reliance on third parties for the manufacture and supply its product candidates for clinical trials; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of Denali's collaboration agreements; Denali's dependence on successful development of its BBB platform technology; Denali's ability to conduct or complete clinical trials on expected timelines; 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 From 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.

Contacts:

Lizzie Hyland

(646) 495-2706

lhyland@gpg.com

or

Morgan Warners

(202) 295-0124

mwarners@gpg.com

Source: Denali Therapeutics Inc.