



Denali Therapeutics Announces FDA Clinical Hold on DNL919 Investigational New Drug (IND) Application

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SOUTH SAN FRANCISCO, Calif., Jan. 13, 2022 (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 that after the close of business (Eastern Time) on Wednesday, January 12, 2022, the company was informed via e-mail communication from the U.S. Food and Drug Administration (FDA) that the DNL919 (ATV:TREM2) Investigational New Drug (IND) application has been placed on clinical hold. The FDA indicated they will provide an official clinical hold letter to Denali in approximately 30 days. Denali plans to provide additional updates pending discussion with the FDA.

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 business strategy and plans; plans timelines and expectations relating to the development of DNL919 and the Antibody Transport Vehicle (ATV), including plans to initiate first in-human trials; the FDA's communication plans related to the clinical hold on the DNL919 Investigational New Drug Application (IND); and Denali's plans and expectations for discussions with the FDA and the outcomes from the discussions. 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: any and all risks to Denali's business and operations caused directly or indirectly by the evolving COVID-19 pandemic; risk of the occurrence of any event, change or other circumstance that could give rise to the termination of Denali's agreements with its collaborators; Denali's early stages of clinical drug development; Denali's and its collaborators' ability to complete the development and, if approved, commercialization of its product candidates; Denali's and its collaborators' 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; Denali's dependence on successful development of its blood-brain barrier platform technology and its programs and product candidates; Denali's and its collaborators' ability to conduct or complete clinical trials on expected timelines; the risk of significant adverse events, toxicities or other undesirable side effects; the risk that preclinical profiles of Denali's product candidate DNL919 may not translate in clinical trials; the potential for clinical trials of Denali's product candidates to differ from preclinical, early clinical, preliminary or expected results; the uncertainty that product candidates including DNL919 will receive regulatory approval necessary to initiate human clinical studies or be commercialized; uncertainty in the FDA's plans to communicate and discuss the clinical hold on the DNL919 IND with Denali and the risk that those discussions may be delayed; the uncertainty in the outcome of Denali's discussions with the FDA regarding the clinical hold on the DNL919 IND; 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. 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 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 November 4, 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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Source: Denali Therapeutics Inc.