



Denali Therapeutics Announces First Patient Dosed in Phase 1b Study of DNL747 for ALS

January 8, 2019

SOUTH SAN FRANCISCO, Calif., Jan. 08, 2019 (GLOBE NEWSWIRE) -- [Denali Therapeutics Inc.](#) (NASDAQ: DNLI), a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases, today announced initiation of dosing in a Phase 1b clinical study of DNL747 in patients with ALS, in collaboration with its partner Sanofi.

"Based on Phase 1 data in healthy volunteer subjects demonstrating DNL747's excellent CNS penetration, safety profile, and ability to inhibit the RIPK1 pathway, we are excited to evaluate DNL747 in ALS patients," said Carole Ho, M.D., Chief Medical Officer of Denali. "The primary purpose of this Phase 1b study is to gain additional safety and biomarker data in ALS patients to support dose selection. The results from this study will inform decisions by Denali and our partner Sanofi on further clinical testing of DNL747, including potential registrational trials."

RIPK1, receptor-interacting serine/threonine-protein kinase 1, is a critical signaling protein in the TNF receptor pathway, which regulates inflammation and cell death in tissues throughout the body. Denali, together with its partner Sanofi, is investigating several molecules targeting RIPK1 for multiple indications, including DNL747 for ALS.

About the DNL747 Phase 1b study in ALS

This study (NCT03757351) is a 28-day, randomized, double blind, placebo controlled cross over design Phase 1b clinical trial in patients with ALS. Its purpose is to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and target and pathway engagement biomarkers in the CSF and blood for DNL747. Up to 26 patients in the study will be randomized to receive either DNL747 or placebo in a cross over design study.

Data readout from this Phase 1b study is expected during Q4 2019. Further details are available at [ClinicalTrials.gov](#).

About Denali

Denali is a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases. Denali pursues new treatments by rigorously assessing genetically validated targets, engineering delivery across the blood-brain barrier and guiding development with biomarker monitoring to demonstrate target engagement and select patients. 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 and expectations by Denali and its partner Sanofi regarding, and implications and purposes of, the Phase 1b clinical study of DNL747 in patients with ALS; expectations regarding patient enrollment in, and the timing of results of, such study; expectations for future clinical development activities; Denali's belief that inhibition of RIPK1 may have therapeutic benefit in several disease indications; and statements made by Denali's CMO. 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 ability to complete the development and, if approved, commercialization of its product candidates; Denali's dependence on successful development of its BBB platform technology and product candidates currently in its core program; Denali's ability to enroll patients in, conduct, or complete, clinical trials on expected timelines; the uncertainty that any of Denali's product candidates will receive regulatory approval necessary to be commercialized; Denali's partnership with Sanofi and Sanofi's intentions regarding future development of DNL747; 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; and other risks, including those described in Denali's Annual Report on Form 10-K filed with the SEC on March 19, 2018, Denali's Quarterly Report on Form 10-Q filed with the SEC on November 8, 2018 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.