



Denali Therapeutics Announces That Its Partner Sanofi has Commenced Dosing of DNL758 in a Phase 1 Study

August 5, 2019

- *Sanofi has commenced dosing of DNL758 in a Phase 1 healthy volunteer study.*
- *DNL758 is an investigational small molecule RIPK1 inhibitor that does not cross the blood-brain barrier, and is intended for peripheral diseases.*
- *Denali will receive a \$10 million clinical milestone payment from Sanofi.*

SOUTH SAN FRANCISCO, Calif., Aug. 05, 2019 (GLOBE NEWSWIRE) -- Denali Therapeutics Inc. (NASDAQ: DNLI), a biopharmaceutical company developing a broad portfolio of product candidates for neurodegenerative diseases, today announced that its partner Sanofi has commenced dosing of DNL758, a peripherally restricted small molecule inhibitor of RIPK1, in a Phase 1 healthy volunteer study. This triggers a milestone payment of \$10 million to Denali according to the Sanofi Collaboration Agreement for RIPK1 inhibitors.

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 and Sanofi are developing several molecules targeting RIPK1 inhibition, including DNL747 in neurological indications and DNL758 in several non-neurological indications.

"We believe that inhibition of RIPK1, a known target in the TNF pathway, has a compelling scientific rationale in autoimmune diseases," said Ryan Watts, Ph.D., CEO. "While Denali will remain focused on defeating neurodegeneration, we are thrilled that our partner Sanofi has commenced clinical studies with DNL758, to investigate its potential in peripheral diseases."

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 to further progress DNL758 into a Phase 1 clinical study in healthy volunteers, Denali's and its partner Sanofi's plans to develop several molecules targeting RIPK1, Denali's beliefs and expectations regarding the results of clinical testing, Denali's receipt of clinical milestone payments from Sanofi, and statements made by Denali'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, risks related to: the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the Sanofi collaboration agreement; Denali's early stages of clinical drug development; Denali's and its partners' ability to complete the development and, if approved, commercialization of product candidates; Denali's dependence on successful development of its BBB platform technology and product candidates currently in its core program; Denali's and its partners' 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 and its partners' ability to continue to create a pipeline of product candidates or develop commercially successful products; Denali's and its partners' 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 12, 2019, Denali's Quarterly Report on Form 10-Q filed with the SEC on May 8, 2019 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.