



Denali Therapeutics Announces Initiation of Phase 2 Study by Partner Sanofi of RIPK1-Inhibitor DNL758 (SAR443122) in Cutaneous Lupus Erythematosus (CLE) Patients

June 28, 2021

SOUTH SAN FRANCISCO, Calif., June 28, 2021 (GLOBE NEWSWIRE) -- [Denali Therapeutics Inc.](#) (NASDAQ: DNL), a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier (BBB) for neurodegenerative diseases, today announced that its partner Sanofi has commenced dosing in a Phase 2 study of DNL758 (SAR443122), a peripherally-restricted small molecule inhibitor of RIPK1, in patients with cutaneous lupus erythematosus (CLE).

"We are delighted that our collaborators at Sanofi are advancing DNL758 into a Phase 2 study in patients with CLE and are excited about the potential of bringing a life-changing therapy to patients through our partnership," said Ryan Watts, Ph.D., Denali's Chief Executive Officer.

Denali and Sanofi entered into a broad collaboration in October 2018 for the global development and commercialization of RIPK1 inhibitors. This includes peripherally restricted molecules such as DNL758 and CNS-penetrant molecules such as DNL788 (SAR443820), which is being evaluated in a Phase 1 study in healthy volunteers with potential development for neurological indications such as amyotrophic lateral sclerosis, multiple sclerosis and Alzheimer's disease. Under the agreement, Denali will receive a milestone payment of \$15 million related to the Phase 2 study with DNL758 from Sanofi. Sanofi is responsible for the development and commercialization of DNL758 and covers all costs related to DNL758. Denali is entitled to receive development, regulatory and sales milestone payments and royalties on product sales.

RIPK1 is a critical signaling protein in the tumor necrosis factor (TNF) receptor pathway and is a regulator of inflammation and cell death. CLE is a type of interface dermatitis characterized by immune cell infiltration, and inhibition of RIPK1 activity is considered a novel approach to modulate the pathophysiology of CLE. Further information on the Phase 2 clinical study of DNL758 for CLE (study number NCT04781816) can be accessed on the ClinicalTrials.gov website or by clicking [here](#).

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 progress, business plans, business strategy, product candidates, planned preclinical studies and clinical trials and expected milestones; the potential benefits, expectations and results of the collaboration with Sanofi; plans to conduct clinical development activities and commercialize products; RIPK1 inhibitors as therapy for cutaneous lupus erythematosus, amyotrophic lateral sclerosis, multiple sclerosis and Alzheimer's disease; plans, timelines and expectations of both Denali and Sanofi related to DNL758, including with respect to the Phase 2 clinical trial in cutaneous lupus erythematosus; plans, timelines and expectations of both Denali and Sanofi related to DNL788, including with respect to results of the Phase 1 trial in healthy volunteers and potential initiation of clinical development for amyotrophic lateral sclerosis, multiple sclerosis and Alzheimer's disease; Denali's priorities, regulatory approvals, timing and likelihood of success and expectations regarding collaborations; 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 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 Sanofi or any of Denali's other collaboration agreements; Denali's early stages of clinical drug development; Denali's and its partners' ability to complete the development and, if approved, commercialization of its product candidates; 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; Denali's and its partners' ability to conduct or complete clinical trials on expected timelines; the risk that preclinical profiles of Denali's product candidates may not translate in clinical trials; the potential for clinical trials or clinical trials of any other product candidates to differ from preclinical, preliminary or expected results; 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; 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 blood-brain barrier platform technology; and other risks, including those described in Denali's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 5, 2021, 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.

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Source: Denali Therapeutics Inc.