



Denali Therapeutics Announces First Patient Dosed in Phase 1b Study of DNL151 for Parkinson's Disease and Launch of Its Engage Parkinson's Website

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- Phase 1b study of DNL151 includes Parkinson's disease patients with and without a genetic LRRK2 mutation
- Either DNL151 or DNL201 anticipated to be selected for potential registrational clinical trials in 2020
- The Engage Parkinson's website provides patients, caregivers and others information on Denali's investigational studies as well as developments in Parkinson's disease and Denali's approach to treating the disease

SOUTH SAN FRANCISCO, Calif., Sept. 04, 2019 (GLOBE NEWSWIRE) -- [Denali Therapeutics Inc.](#) (NASDAQ: DNL1), a biopharmaceutical company developing a broad portfolio of product candidates for neurodegenerative diseases, today announced initiation of dosing in a Phase 1b clinical study of LRRK2 inhibitor DNL151 in patients with Parkinson's disease, and the launch of its Engage Parkinson's website.

"Based on data generated from our prior study in healthy volunteer subjects, we are excited to evaluate DNL151 in Parkinson's disease patients," said Carole Ho, M.D., CMO. "We believe that this study will provide additional important safety and biomarker data in patients to inform the choice between either DNL151 or DNL201 for potential registrational trials."

DNL151 is a small molecule inhibitor of leucine-rich repeat kinase 2 (LRRK2). LRRK2 is a regulator of lysosomal function, which is impaired in Parkinson's disease and may be restored by LRRK2 inhibition. Inhibition of LRRK2 activity may potentially slow the progression of disease in all patients with Parkinson's disease based on restoration of lysosomal function.

"We are encouraged by the progress with our LRRK2 clinical program," said Ryan Watts, Ph.D., CEO. "The launch of our Engage Parkinson's website is intended to strengthen our engagement and interactions with the Parkinson's disease patient community. This is an important part of our efforts to connect with patients who may be eligible for our current and future clinical trials."

About the DNL151 Phase 1b study

This study ([NCT04056689](#)) is a 28-day, multicenter, randomized, placebo controlled, double-blind Phase 1b clinical trial in patients with mild to moderate Parkinson's disease, with and without genetic LRRK2 mutations. Its purpose is to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, target and pathway engagement biomarkers as well as certain exploratory clinical endpoints, in multiple oral doses of DNL151. Patients in the study will be randomized to receive either a low dose of DNL151, a high dose of DNL151, or a placebo. It is expected that total enrollment for the study will be 24 patients.

Data readout from this study is expected to be presented in early 2020. Further details are available at [ClinicalTrials.gov](#).

About the [EngageParkinsons.com](#) Website

[EngageParkinsons.com](#) – The Denali Parkinson's disease patient engagement website provides patients, caregivers, healthcare professionals, and advocates an online destination for emerging information about Parkinson's disease. In addition, Engage Parkinson's describes Denali's biomarker-driven approach in discovering and developing investigational therapies for Parkinson's patients.

Engage Parkinson's provides an avenue for registrants to engage with Denali's team to learn more about Denali sponsored clinical trials, including clinical studies in [DNL151](#) and [DNL201](#) in Parkinson's patients with and without the LRRK2 mutation. [Registrants](#) will also receive communications from Denali on progress in emerging Parkinson's research and development insights, including information regarding future Denali investigational studies.

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 through biomarkers that 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 to progress DNL151 or DNL201 into a registrational clinical study in Parkinson's disease patients in 2020; expectations regarding what the results will inform, expectations regarding patient enrollment in, and the timing of results of, such study; Denali's plans to conduct further clinical testing in this area; and statements made by Denali's CMO and 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: 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 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 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, 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 August 6, 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.

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