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Denali Therapeutics announces Phase 1B Study of DNL747

11 January 2019 | News | By Kalyani Sharma

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Denali Therapeutics Inc., a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases has announced initiation of dosing in a Phase 1b clinical study of DNL747 in patients with ALS, in collaboration with its partner Sanofi.

Carole Ho, Chief Medical Officer of Denali said, “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.

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.

DNL747 Phase 1b study in ALS 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.