Progentos Therapeutics Announces First Participant Dosed in Phase 1/2a Study of PRO-1562 for Remyelination in Multiple Sclerosis

CAMBRIDGE, Mass.-- Progentos Therapeutics, a biotechnology company developing regenerative medicines for multiple sclerosis (MS) and other demyelinating diseases, today announced that the first participant has been dosed in its Phase 1/2a clinical trial of PRO-1562 (NCT07826689). PRO-1562 is a novel oral small molecule designed to regenerate myelin in patients with demyelinating diseases, like MS, with the potential to protect neuroaxonal integrity and restore neurologic function.

The Phase 1 portion of the trial is a randomized, double-blind, placebo-controlled single-ascending-dose study being conducted in healthy adults at a single site in Australia. The study will characterize the safety, tolerability, pharmacokinetics and CNS penetrance of PRO-1562. The Phase 2a portion is a six-month randomized, double-blind, placebo-controlled, dose-ranging trial of once monthly PRO-1562 in adults with relapsing multiple sclerosis (RMS) and chronic optic neuropathy to demonstrate remyelination using electrophysiologic, MRI and clinical measures.

“This milestone is a significant step forward in translating promising remyelination science into a potential therapy for people living with MS,” said Paul Frohna, M.D., Ph.D., Chief Medical Officer of Progentos Therapeutics. “Disease-modifying immunomodulatory therapies have transformed the treatment of MS by reducing relapses and controlling inflammatory disease activity, yet many patients still accumulate neurological damage and disability over time. Today, there are no approved therapies to regenerate lost myelin. The preclinical data with PRO-1562 suggest that our novel remyelinating approach has the potential to fundamentally alter the treatment paradigm for patients with MS and improve their long-term prognosis.”

About PRO-1562

PRO-1562 is a first-in-class small molecule designed to regenerate myelin and potentially protect neuroaxonal integrity and restore neurologic function in patients with Multiple Sclerosis. MS is a chronic immune-mediated disease of the central nervous system in which damage to myelin, the protective sheath surrounding nerve fibers, disrupts communication between the brain and the body and leaves axons

vulnerable to further injury and degeneration. In preclinical studies, PRO-1562 induces endogenous oligodendrocyte precursor cells to differentiate into new oligodendrocytes and promotes remyelination in preclinical models of chronic demyelination. Further, PRO-1562 increased myelination in both white and gray matter, potentially increasing sensory, motor and cognitive function. PRO-1562 promotes oligodendrocyte differentiation across multiple species and has an encouraging pre-clinical safety profile.

More information on the study can be found at clinicaltrials.gov

About Progentos Therapeutics

Progentos is developing first-in-class compounds to induce endogenous oligodendrocyte progenitor cells to remyelinate axons in patients suffering from MS and other demyelinating diseases. Combining expertise in chemistry and *in vitro* and *in vivo biological* models, Progentos discovers and develops novel small-molecule drugs to regenerate tissues in patients with degenerative diseases. The company was funded by a syndicate of investors led by Forbion and has operations in Cambridge, MA, USA and Naarden, The Netherlands. More information can be found at www.progentos.com

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