Muna Therapeutics Announces First Subjects Dosed in Phase 1 Trial of Novel Oral TREM2 Agonist for Early Alzheimer's Disease

MNA-001 has best-in-class potential based on preclinical data demonstrating ability to significantly reduce neurotoxic amyloid burden and reprogram microglia to protective states

Phase 1 study initiated to assess safety, tolerability, pharmacokinetics and pharmacodynamic effects of MNA-001 on biomarkers of TREM2 target engagement and activation, with topline data expected mid 2026

Achievement marks Muna's evolution into a clinical-stage company

COPENHAGEN, Denmark, November 10, 2025 – Muna Therapeutics, a clinical stage biotechnology company focused on developing innovative therapeutics for neurodegenerative diseases, today announced that the first subjects have been dosed in a Phase 1 single-ascending dose/multiple-ascending dose study of lead asset MNA-001 in healthy adult participants. MNA-001 is a novel potent, selective and orally administered small molecule "triggering receptor expressed on myeloid cells 2" (TREM2) agonist with best-in-class potential for the treatment of early Alzheimer's and other neurodegenerative diseases.

"We are delighted to have initiated clinical development of MNA-001. Our goal is to fundamentally shift the focus in Alzheimer's disease treatment from clearing pathology to bolstering the brain's innate protective mechanisms," said Rita Balice-Gordon, Ph.D., Muna's Chief Executive Officer. "This milestone demonstrates our progress toward advancing disease-modifying therapeutics that mitigate key drivers of neurodegeneration and functional impairment to improve disease outcomes."

MNA-001 is designed to activate TREM2, a critical regulator of microglia, which are brain cells with immune and other functions. By boosting TREM2 signaling, MNA-001 enhances protective microglial responses to pathology, promoting the phagocytosis of toxic misfolded proteins and cell debris to slow or stop the progression of neurodegeneration. MNA-001's best-in-class potential is supported by a strong preclinical data package demonstrating the significant reduction of amyloid pathology and reprogramming of disease-associated microglia to homeostatic, protective states in animal models of Alzheimer's pathology. The molecule was shown to be safe and well tolerated in preclinical toxicology studies.

The primary objective of Muna's Phase 1 randomized, double-blind, placebo-controlled

study is to evaluate the safety and tolerability of MNA-001 in healthy adult and elderly subjects. The study will also assess pharmacokinetics and the pharmacodynamic effects of MNA-001 on biomarkers of TREM2 engagement and activation in plasma and CSF. It also will leverage Muna's novel biomarker discoveries to provide early insights into MNA-001's activity in humans, with topline data expected in late summer, 2026.

"We believe that MNA-001 has the potential to treat disease and improve quality of life for Alzheimer's patients and their loved ones," said Donald Nicholson, Ph.D., Chair of Muna's Board of Directors. "We intend for this to be the first of several innovative approaches to enhance the brain's resilience to pathological drivers of neurodegeneration."

About Muna Therapeutics
Muna Therapeutics is pioneering a new era of drug discovery for neurodegenerative diseases by focusing on enhancing resilience to the effects of misfolded protein pathology to protect brain functions like cognition. Muna's all-in-human discovery engine identifies new therapeutic targets that can enhance the brain's innate protective mechanisms. Muna—which means 'to remember' in Old Norse—is developing a portfolio of therapeutics to slow or stop devastating diseases like Alzheimer's and other neurodegenerative disorders. For more information, visit www.munatherapeutics.com. Follow Muna on LinkedIn.

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