PhenoNet, Initiating A Phase IIb study in ALs Subjects

Our current clinical study targets early-stage patients with defined progression profiles, representing a more precise approach to developing ALS drugs.

CAMBRIDGE, MA, UNITED STATES, November 4, 2025 /EINPresswire.com/ --

Cambridge, MA-based PhenoNet, Inc., announced today that it has received an IND activation and clearance to initiate a Phase IIb study for its lead program, PHENOGENE-1A. PhenoNet Inc. received FDA notification on May 9, 2025, “May Proceed” to initiate a Phase IIb Clinical Study for adjuvant therapy targeting Amyotrophic Lateral Sclerosis (ALS, Lou Gehrig’s Disease), in mild to moderate subjects.

PHENOGENE-1A is a multifunctional therapy based on a repurposed drug with a known safety profile, formulated with novel targeted delivery technology. This approach is designed to achieve therapeutic concentrations in both blood and brain, where it acts on key mechanisms involved in neuroinflammation and neurodegeneration. Developed to slow or halt the progression of ALS, PHENOGENE-1A has demonstrated a favorable safety and tolerability profile in preclinical studies and early clinical testing. The treatment is designed to improve the quality of life for patients, their families, and caregivers.

“Addressing the triggers and progression of ALS with a multifunctional therapeutic approach offers a new strategy to modify the disease course,” said Dr. David R. Elmaleh, PhenoNet Founder and Chairman. “Very early intervention in patients with the first clinical signs of muscle function loss is key to preventing or delaying disease progression. Our in-vitro work, in-vivo ALS animal models, and data from a Phase IIa cohort support advancing PHENOGENE-1A into this Phase IIb trial.”

“ALS-modifying therapies that work alongside standard of care and target the underlying pathophysiology of the disease can add significant value to existing treatment options,” added Dr. Atul Gupta, Chief Medical Officer of PhenoNet. “If successful, our multifunctional therapy has

the potential for long-term benefits in slowing ALS progression." Dr. Gupta has extensive experience in neurodegenerative disease trials and will serve as a principal safety monitor and investigator in the study.

"I am truly excited to serve as Principal Investigator of this Phase IIb study, as it holds the potential to advance a promising new therapy and contribute meaningfully to the treatment landscape for ALS," said Dr. Björn Oskarsson, neurologist, ALS expert, Mayo Clinic-Florida.

"PhenoNet's proprietary technology includes intellectual property covering the drug, dosing, formulation, and delivery to ensure penetration to both blood and brain," said Dr. Peter Conti, Professor of Radiology, Pharmacology, and Pharmaceutical Sciences at the Keck School of Medicine and the USC Mann School of Pharmacy. Dr. Conti, a neuroanatomist and expert in early neurodegenerative diagnostics, serves as a key scientific advisor to the company.

PhenoNet reports that first patient screening was initiated on October 30, 2025, for the trial titled: "A Phase IIb Randomized, Double-Blind, Placebo-Controlled, Multi-Dose Study to Evaluate the Effects of PHENOGENE-1A as an Adjuvant Treatment in Subjects with Mild to Moderate ALS. (ClinicalTrials.gov Identifier: NCT 07142291)

The Phase IIb trial will be conducted across the U.S. and Europe. The company intends to pursue a Special Protocol Assessment (SPA) with the FDA and, if successful, will design this trial to support a future 505(b)(2) NDA submission.

About PhenoNet, Inc.
PhenoNet (www.phenonet.us) is a privately held biotechnology company headquartered in Cambridge, Massachusetts. The company is advancing the development and commercialization of PHENOGENE drugs for the treatment of neurodegenerative diseases such as Alzheimer's disease (AD) and ALS. Its lead candidate, PHENOGENE-1A for ALS and for early AD, non-APOE4 patients, is designed to modify disease progression by addressing neuroinflammation and other key triggers of degeneration. PhenoNet aims to transform treatment approaches for patients facing urgent, unmet medical needs.
Except for FDA approval information contained in this press release, forward-looking statements are primarily dependent on the success of our lead product candidate. We may not be able to commercialize these potential products successfully. Among other reasons, failure may depend on the conduct and results of clinical trials, FDA requirements, the non-completion of our drugs in development, competing products, secured financing, unforeseen market conditions, and future events that could hinder commercialization.

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