Therini Bio Announces First Patient Dosed in Phase 1b Trial of THN391 in Alzheimer's Disease

- Pioneering approach to halting the chronic neuroinflammation responsible for neurodegeneration
- Trial to assess safety, PK and detect early signs of efficacy
- Initial data expected in mid-2026

Sacramento, July 29, 2025 (GLOBE NEWSWIRE) - Therini Bio, Inc., a clinical-stage biotech company developing fibrin-targeting immunotherapies for neurodegenerative diseases driven by vascular dysfunction today announced that the first patient has been dosed in a Phase 1b trial evaluating THN391 for the treatment of Alzheimer's disease (AD). Therini's novel approach aims to target chronic neuroinflammation responsible for neuronal loss in neurodegenerative disorders, including AD.

THN391 is a potential first-in-class, high-affinity, humanized monoclonal antibody designed to selectively target the inflammatory epitope on fibrin to treat inflammatory neurodegenerative diseases. THN391 demonstrated activity in preclinical studies in AD models in protecting against neuronal degeneration by blocking the activation of inflammatory cascades caused by toxic fibrin deposits. In a recent Phase 1a, randomized, double-blind, placebo-controlled, healthy volunteer trial, THN391 was shown to be well-tolerated, with no serious or drug related adverse events reported and had no adverse effects on coagulation. THN391 also exhibited dose proportional pharmacokinetics (PK) and a 40-day half-life that supports monthly dosing.

The Phase 1b randomized, double-blind, placebo-controlled trial will assess the safety, tolerability and PK of multiple ascending doses of THN391 in patients aged 65-85 years old with early AD and vascular risk factors. The trial will consist of at least three (3) dose cohorts with the patients in each cohort receiving three (3) monthly doses of THN391 or placebo and follow-up evaluation out to five (5) months. In addition to analyzing safety and PK data, biological and clinical endpoints will be assessed, utilizing pharmacodynamic disease biomarkers in plasma and cerebrospinal fluid, MRI imaging and cognitive assessments. Initial data is expected to be available in mid-2026.

Brad Navia, M.D., Ph.D., Chief Medical Officer – Neurology of Therini Bio, an internationally recognized expert in neuroscience research, clinical development and brain imaging, whose previous experience includes leading programs at Johnson & Johnson, Eisai Pharmaceuticals and Sunovion Pharmaceuticals, said, "THN391 represents a promising new approach to treating Alzheimer's disease by directly addressing one of its primary causes, neuroinflammation. Its development also comes at an exciting time in the field as more research emerges on the important role of vascular dysfunction in AD. The flexible design of this Phase 1b trial enables us to engage an early AD population known to have vascular risk factors and employ innovative biomarkers aimed at detecting early signs of efficacy in the hopes of rapidly advancing this novel treatment towards providing relief for patients and families struggling with this dreadful disease."

About

Therini Bio is a clinical-stage biotech company developing immunotherapies for neuroinflammation in diseases driven by vascular dysfunction. Therini Bio is developing a pipeline of potential first-in-class therapies selectively targeting toxic fibrin accumulation for diseases, including Alzheimer's disease and Diabetic Macular Edema, where destructive neuroinflammation plays a central role in the disease process. Therini Bio's top-tier syndicate of life sciences investors includes the Alzheimer's Drug Discovery

Foundation, Angelini Ventures, Apollo Health Ventures, SV Health Investors' Biotech Fund and Dementia Discovery Fund, Dolby Family Ventures, Dreavent Biotech Investments, Eli Lilly and Company, Foundation for a Better World, MRL Ventures Fund, the therapeutics-focused corporate venture fund of Merck & Co., Inc., and Sanofi Ventures. For more information, visit www.therinibio.com.

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