Source: Therini Bio, Inc.

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Therini Bio Announces Interim Results from the Phase 1 Trial of THN391 for the Potential Treatment of Dementia

- THN391 was found to be safe and well-tolerated -- THN391 demonstrated a prolonged half-life and dose proportional Cmax levels -- The data will be presented October 25-27th at CTAD 2023 -

SACRAMENTO, Calif., Oct. 24, 2023 (GLOBE NEWSWIRE) -- Therini Bio, Inc., a biotech company focused on developing fibrin targeted therapies to treat inflammatory neurodegenerative and retinal diseases, today announced interim results from the Phase 1 trial of its lead candidate, THN391, for the treatment of dementia. The data will be detailed in a poster presentation at the 16th Clinical Trials on Alzheimer's Disease (CTAD) conference taking place from October 25-27, 2023, in Boston, MA.

Vascular dysfunction is a key driver in many neurodegenerative diseases, with fibrin playing a major role. Fibrin is a protein that is essential for blood clotting, but factors such as aging, vascular and rheumatological diseases and genetic risks, have shown fibrin to also cause chronic neuroinflammation and innate immune activation, resulting in severe retinal and neurological diseases, including Alzheimer's. THN391 is a potential first-in-class, therapeutic, monoclonal antibody that is designed to target the inflammatory properties of fibrin without disrupting coagulation and protective innate immunity.

The Phase 1 trial evaluating THN391 consists of single ascending dose (SAD) and multiple ascending dose (MAD) portions, which are designed to study the safety and tolerability of THN391 in healthy subjects, as well as to collect pharmacokinetic and immunogenic measures.

At the data cut-off date, the first three cohorts (0.3 mg/kg, 1.0 mg/kg, 3.0 mg/kg) of eight subjects each (n=24) had received a single dose of THN391. No drug related adverse events were reported and the therapy was found to be well-tolerated. In addition, dose proportional Cmax levels were observed. Data from the first two cohorts, 0.3 mg/kg and 1.0 mg/kg, demonstrated a half-life of approximately 50 days in both groups. Data from the 3.0 mg/kg cohort continues to mature and additional SAD 10 mg/kg and MAD 3.0 mg/kg cohorts have been initiated.

"We are truly encouraged by the results of our promising early clinical data, which has correlated extremely well to our preclinical work," said Jeffrey Stavenhagen, Ph.D., Chief Scientific Officer of Therini Bio. "The safety profile and extended half-life observed in these initial cohorts has emboldened us further to investigate a once-monthly or greater dosing schedule and implement a clinical plan that optimally drives development of THN391 for the treatment of dementia forward. We believe that THN391's ability to block fibrin-mediated neuroinflammation has the potential to change the lives of millions of people around the world."

Presentation Details:

Theme: Beyond Amyloid and Tau

Title: Translation Studies and Clinical Development of THN391, a Novel Anti-Fibrin Antibody for the

Treatment of Dementia
Poster Number: P200

Presenter: Jeffrey Stavenhagen, Ph.D., Chief Scientific Officer of Therini Bio

Date and Location: The poster will be on display from 7:30 a.m. ET on Wednesday, October 25, 2023, until 4:30 p.m. ET on Friday, October 27, 2023, in the Poster Hall at the Boston Park Plaza Hotel, and will also be available on the CTAD23 digital platform, www.ctad23.com, at 9:00 a.m. ET on Tuesday, October 24, 2023.

The poster will be accessible to the public on Saturday, October 28, 2023, at 10:00 a.m. ET at www.ctad-alzheimer.com and in the *Publications* section of www.therinibio.com.

About Therini Bio, Inc.

Therini Bio is a biotech company focused on developing fibrin-targeted therapies to treat inflammatory neurodegenerative and retinal diseases. The Company is developing a pipeline of potential first-in-class therapies targeting toxic fibrin accumulation, for diseases including Alzheimer's disease (AD), multiple sclerosis (MS), as well as in a variety of retinal diseases, such as diabetic macular edema (DME) where destructive inflammation plays a role in the disease process. The foundational science was licensed based on technology discovered in Katerina Akassoglou, Ph.D. laboratories at the Gladstone Institutes at the University of California San Francisco (UCSF) and formerly the University of California San Diego (UCSD). Therini Bio's top-tier syndicate of life sciences investors includes the Alzheimer's Drug Discovery Foundation, Dementia Discovery Fund, Dolby Family Ventures, Eli Lilly and Company, Foundation for a Better World, MRL Ventures Fund, Sanofi Ventures and SV Health Investors' Impact Medicine Fund. For more information, visit www.therinibio.com.

NIH Disclosure

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