T3D Therapeutics, Inc. Receives FDA IND Approval to Begin Phase 2 Clinical Study of T3D-959 in Alzheimer's Patients

Phase 2a Clinical Trial of a Novel Nuclear Receptor Agonist in Alzheimer's patients expected to initiate in 3Q2015.

Research Triangle Park, NC (PRWEB) June 22, 2015 -- T3D Therapeutics, Inc., a Research Triangle Park, NC-based developer of Alzheimer's disease therapies, announced today that the Division of Neurology Products of the U.S. Food and Drug Administration has approved the company's Investigational New Drug (IND) application to begin a Phase 2a clinical study of T3D-959, the company's lead product candidate, in patients with mild-to-moderate Alzheimer's disease.

Commenting on the approval, T3D Therapeutics' CEO John Didsbury said, "We are pleased to have received FDA clearance to begin our Phase 2a clinical study and look forward to initiating the study. This is a significant milestone for our company."

The Phase 2a clinical study will evaluate the T3D-959 product candidate directly in patients with mild-to-moderate Alzheimer's disease. In addition to evaluating the safety of the product candidate in these patients, the study is designed to examine changes in cerebral glucose metabolism by FDG-PET and neural connectivity by BOLD fMRI. The study is a randomized, parallel, 4-dose design. T3D Therapeutics, Inc. expects to enroll 36 patients in the single-center study. Jason Kralic, Ph.D., former Head of Neurosciences Business Development, Worldwide Business Development, GlaxoSmithKline, Inc. and T3D Advisory Board member said, "This Ph2a study leverages leading-edge translational medicine techniques to demonstrate evidence for both the mechanism of action and efficacy for T3D's novel approach to treatment of patients with AD."

T3D-959 is a promising new, and potentially disease-modifying therapeutic for Alzheimer's disease designed to be administered orally as a projected once-a-day drug therapy. The drug has displayed multi-faceted effectiveness on memory, motor function, inflammation, neuronal cell death, beta amyloid production and tau alteration in pre-clinical studies. T3D Therapeutics, Inc. has been selected by the Alzheimer's Association to present these pre-clinical results of T3D-959 at the upcoming Alzheimer's Association International Conference (AAIC) in Washington, DC, July 18-23, 2015. The abstract entitled "T3D-959; A Multi-Faceted Disease Remedial Drug Candidate for the Treatment of Alzheimer's Disease," has been selected for presentation in the session on Developing Topics, a session designed to bring the latest research findings in the field to AAIC attendees.

About T3D Therapeutics:
T3D Therapeutics Inc. is a privately-held Research Triangle Park, NC-based company incorporated in 2013. The company is committed to developing disease remedial therapeutics for the treatment of Alzheimer's disease and other CNS disorders. T3D-959, its lead product candidate, has successfully concluded Phase 1 clinical trials.

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