TransTech Pharma Completes End of Phase 2 Meeting with FDA for TTP488

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TransTech Pharma Inc. announced today that it has successfully completed an End of Phase 2 meeting for TTP488 with the U.S. Food and Drug Administration (FDA). TTP488 is under development for the treatment of mild to moderate Alzheimer's disease. The FDA Division of Neurology Products agreed that the data from the completed Phase 2 clinical trial is sufficient to support the start of a Phase 3 registration program. The FDA concurred with TransTech's proposal for the overall size and design of the planned Phase 3 clinical studies, the primary endpoints, the total safety database proposed for NDA filing, the clinical pharmacology program and the plan to apply for a Special Protocol Assessment ("SPA").

The Phase 3 clinical trial design for TTP488 will focus on patients with mild to moderate Alzheimer's disease. TransTech Pharma anticipates filing an SPA request within the next few weeks.

"We are very pleased with the outcome of the End of Phase 2 meeting and look forward to working with the FDA to finalize the Phase 3 study design via the FDA's Special Protocol Assessment program," said Dr. Adnan Mjalli, TransTech's Chief Executive Officer. "This development represents another significant step in advancing the development of TTP488 toward meeting the huge unmet medical need for treatment of patients with Alzheimer's disease.

About TTP488

Substantial data suggest that "RAGE" molecules are involved in the pathogenesis of Alzheimer's disease, and that sustained amyloid beta interaction with RAGE at the blood-brain barrier (BBB), or in neuronal or microglial cells, is an important element of amyloid plaque formation and chronic neural dysfunction.

TTP488 is a novel, small-molecule, orally active antagonist of RAGE. In a recent double-blind clinical trial where data was taken over 18 months, TTP488 slowed cognitive decline in patients with mild to moderate Alzheimer's disease. TransTech Pharma discovered and developed TTP488 using its proprietary drug discovery platform, TTP Translational Technology®.

About Alzheimer's Disease

Alzheimer's disease, the most common form of dementia, is a progressive neurodegenerative disorder that causes decline in cognition and functional abilities. It has been estimated to affect 5 million individuals in the United States, and represents the 6th leading cause of death. Worldwide, there are currently more than 35 million people with dementia, and the number is predicted to increase to over 115 million by 2050.

While current approved therapies for Alzheimer's disease focus on improving the symptoms of cognitive dysfunction, there is currently no treatment to slow disease progression.

About TransTech Pharma

TransTech Pharma is a privately held, clinical-stage pharmaceutical company focused on the discovery, development, and commercialization of human therapeutics to fill unmet medical needs. The Company's high-throughput drug discovery platform, Translational Technology®, translates the functional modulation of human proteins into safe and effective medicines. TransTech Pharma has a pipeline of small-molecule clinical and pre-clinical drug candidates for the treatment of a wide range of human diseases, including central nervous system disorders, diabetes, obesity, cardiovascular disease, inflammation and cancer. For further company information, visit http://www.ttpharma.com.

Contacts:

Investors

The Trout Group Marc Panoff 646-378-2958

mpanoff@troutgroup.com

Media

BMC Communications
Brad Miles
646-513-3125
bmiles@bmccommunications.com