TransTech Pharma, LLC Announces Agreement with FDA on Special Protocol Assessment for TTP488 Phase 3 Trial in Patients with Mild Alzheimer's Disease

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TransTech Pharma, LLC today announced that it has reached an agreement with the U.S. Food and Drug Administration Division of Neurology Products, under the Special Protocol Assessment (SPA) process, on the design of a single Phase 3 trial of TTP488 for the treatment of patients with mild Alzheimer's disease. A Special Protocol Assessment (SPA) from the FDA is a binding agreement that the Phase 3 trial design, planned execution and statistical analyses are acceptable to support regulatory approval. Additional information regarding the FDA's Special Protocol Assessment process may be found at:

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm080571.pdf

"The agreement on the SPA represents a significant milestone for the development of TTP488 and for TransTech Pharma" said Steve Holcombe, President and CFO. "We are extremely pleased to receive agreement on the SPA and to have a clear path forward for the submission and regulatory approval of TTP488 for the treatment of patients with mild Alzheimer's disease."

The Phase 3 trial will be a randomized, double-blind, placebo-controlled, multi-center study to evaluate the efficacy and safety of TTP488 for the treatment of patients with mild Alzheimer's disease. The trial will compare TTP488 5mg daily to placebo over the course of 18 months of treatment. Approximately 800 patients with mild Alzheimer's disease receiving standard of care (i.e. acetylcholinesterase inhibitors) will be enrolled. The primary efficacy analysis will be based on the changes in ADAS-cog (Alzheimer's Disease Assessment Scale – cognitive subscale) and CDR-sb (Clinical Dementia Rating – sum of boxes). TransTech Pharma anticipates beginning enrollment of patients before the end of the year.

About TTP488

Substantial data suggest that RAGE, the Receptor for Advanced Glycation Endproducts, is involved in the pathogenesis of Alzheimer's disease, and that sustained Ab 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 double-blind clinical trial where data was collected over 18 months, TTP488 slowed cognitive decline in patients with mild to moderate Alzheimer's disease. The effect, while evident in both patients with mild and moderate disease, was more prominent in patients with mild 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 the cognitive dysfunction, there is currently no treatment to slow disease progression.

About TransTech Pharma, LLC

TransTech Pharma, LLC 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, LLC 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.

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