

## **vTv Therapeutics Initiates Pivotal Phase 3 Trial Evaluating Azeliragon for the Treatment of Patients with Mild Alzheimer's Disease**

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### ***Completed Phase 2 Trial Showed Positive Results Combating Alzheimer's Disease***

High Point, North Carolina (May 19, 2015)

vTv Therapeutics LLC (vTv) today announced enrollment of the first patients into STEADFAST (Single Trial Evaluating Alzheimer's Disease Following Addition to Symptomatic Therapy), vTv's Phase 3 placebo controlled trial of azeliragon, an oral antagonist of the Receptor for Advanced Glycation Endproducts (RAGE) for treatment of mild Alzheimer's disease. Phase 3 begins following a Phase 2 trial that demonstrated positive results in slowing cognitive decline with 5 mg/day of azeliragon in patients with mild to moderate Alzheimer's Disease.

"We are excited to reach this next significant milestone in the development of azeliragon as a potential therapy to slow the decline of cognition and function in patients with Alzheimer's disease by enrolling our first patients in our phase 3 trial," said Steve Holcombe, President and CEO of vTv. "There remains a critical need for the development of new treatments for this devastating disease. Azeliragon's novel mechanism allows for targeting a receptor we believe is involved in multiple pathologic processes leading to the development and progression of Alzheimer's disease."

The STEADFAST Study will investigate the efficacy of azeliragon compared with placebo in the treatment of patients with mild Alzheimer's disease already receiving cholinesterase inhibitors and/or memantine.

vTv is actively recruiting and enrolling new patients for the STEADFAST Study. Physicians and researchers looking for more information about the trial can visit [www.livingsteadfast.com](http://www.livingsteadfast.com) or call 336-841-0300 ext 120.

#### **About the STEADFAST Study**

STEADFAST is a randomized, double-blind, placebo-controlled Phase 3 study that is investigating the efficacy of Azeliragon as a potential disease modifying therapy for patients with mild Alzheimer's disease. The trial targets enrollment of 800 patients in the United States and Canada who will receive 18 months of treatment. The protocol is being conducted following agreement with FDA under the Special Protocol Assessment (SPA) process.

#### **About Azeliragon**

A broad range of human pathologic and experimental biologic investigation suggests that RAGE activation contributes to the pathogenesis of Alzheimer's disease. Sustained Amyloid- $\beta$  interactions with RAGE at the blood-brain barrier (BBB) and in neuronal and microglial cells, play potentially major roles in amyloid plaque formation, neuroinflammation and chronic neural dysfunction – all hallmarks of Alzheimer's disease.

Azeliragon, also known as TTP488, is a novel orally active small-molecule antagonist of RAGE. In a double-blind Phase 2 clinical trial where data was collected over 18 months, azeliragon 5 mg/day slowed cognitive decline, as measured by the Alzheimer's Disease Assessment Scale-cognitive cognition (ADAS-cog), in patients with mild to moderate Alzheimer's disease. The effect on cognition, statistically significant in patients with mild-to-moderate disease, was more pronounced in patients with mild Alzheimer's disease. Additionally, effects were noted on the Clinical Dementia Rating sum of boxes (CDR-sb), a measure of global impairment, in patients with mild Alzheimer's disease. vTv discovered and developed azeliragon 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 is estimated to affect 5 million Americans, representing the 6th leading cause of death. Worldwide, there are currently more than 35 million people with dementia and is expected 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 long-term, cognitive decline and disease progression.

### **About vTv Therapeutics LLC**

vTv Therapeutics LLC is a clinical-stage biopharmaceutical company engaged in the discovery and development of orally administered small molecule drug candidates to fill significant unmet medical needs. vTv has a pipeline of clinical drug candidates led by programs for the treatment of Alzheimer's disease and type 2 diabetes as well as treatment of inflammatory disorders and the prevention of muscle weakness. The Company's drug candidates were discovered with its high-throughput drug discovery platform, Translational Technology®, which translates the functional modulation of human proteins into safe and effective medicines. For further company information, visit [www.vtvtherapeutics.com](http://www.vtvtherapeutics.com)

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