



vTv Therapeutics Completes Enrollment of Part A of Pivotal Phase 3 Trial Evaluating Azeliragon for the Treatment of Patients with Mild Alzheimer’s Disease

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Phase 2b Trial Showed Positive Results In Slowing Cognitive Decline

HIGH POINT, N.C.--(BUSINESS WIRE)--Sep. 7, 2016-- vTv Therapeutics Inc. (NASDAQ:VTVT) today announced the completion of enrollment for Part A of 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 follows a Phase 2b trial that demonstrated positive results in slowing cognitive decline with 5 mg/day of azeliragon in patients with mild to moderate Alzheimer’s disease.

“With completion of enrollment of patients in Part A of our Phase 3 trial, we are excited to reach another 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,” 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 targets a receptor that we believe is involved in multiple pathologic processes leading to the development and progression of Alzheimer’s disease.”

The Phase 2b results of 5mg per day of azeliragon over a period of 18 months showed statistically significant benefit in mild-to-moderate Alzheimer’s patients (+3.1 points on ADAS-Cog11 standard measure of cognition) and greater benefit in mild patients (+4.0 points on ADAS-Cog11), with improvements on secondary endpoints including a statistically significant reduction in psychiatric adverse events.

vTv is continuing to recruit and enroll new patients for Part B of the STEADFAST Study. Physicians and researchers looking for more information about the trial can visit www.livingsteadfast.com or call 336-841-0300 ext 120.

About the STEADFAST Study

STEADFAST is a randomized, double-blind, placebo-controlled Phase 3 trial 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 (400 for each Part A and B) in the United States and Canada who will receive 18 months of treatment. Enrollment of Part B will be expanded to include study sites in the United Kingdom, Australia, New Zealand and South Africa. Subjects completing the STEADFAST trial may be eligible to enroll in a 24-month open-label extension trial. STEADFAST is being conducted following agreement with FDA under the Special Protocol Assessment (SPA) process with fast track status. Data from Part A of the trial is expected to read out in early 2018 with Part B in late 2018.

About Azeliragon

vTv discovered and developed azeliragon using its proprietary drug discovery platform TTP Translational Technology®. A broad range of human pathologic and experimental biologic investigation suggests that RAGE activation contributes to the pathogenesis of Alzheimer’s disease. Sustained Amyloid-β 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.

About vTv Therapeutics Inc.

vTv Therapeutics Inc. 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. Last month, vTv announced positive topline results from a placebo and active-comparator-controlled Phase 2b clinical study of TTP399, a liver-selective glucokinase activator (GKA) under development for the treatment of Type 2 diabetes.

The Company’s drug candidates were discovered with its high-throughput drug discovery platform, TTP Translational Technology®, which translates the functional modulation of human proteins into safe and effective medicines. For further company information, visit www.vtvtherapeutics.com.

Forward-Looking Statements

This release contains forward-looking statements, which involve risks and uncertainties. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and, in each case, their negative or other various or comparable terminology. All statements other than statements of historical facts contained in this release, including statements regarding the timing of our clinical trials, our strategy, future operations,

future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause our results to vary from expectations include those described under the heading "Risk Factors" in our Annual Report on Form 10-K and our other filings with the SEC. These forward-looking statements reflect our views with respect to future events as of the date of this release and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this release and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this release. We anticipate that subsequent events and developments will cause our views to change. Our forward-looking statements do not reflect the potential impact of any future acquisitions, merger, dispositions, joint ventures or investments we may undertake. We qualify all of our forward-looking statements by these cautionary statements.

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Source: vTv Therapeutics Inc.

vTv Therapeutics

Investors

IR@vtvtherapeutics.com

or

Media

Nura Strong

PR@vtvtherapeutics.com