

# vTv Therapeutics Completes Enrollment of Part B of Pivotal Phase III STEADFAST Trial Evaluating Azeliragon for the Treatment of Patients with Mild Alzheimer's Disease

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-- Azeliragon is the only RAGE receptor antagonist in clinical development for Alzheimer's Disease --

HIGH POINT, N.C.--(BUSINESS WIRE)--Jun. 1, 2017-- vTv Therapeutics Inc. (vTv) (Nasdaq: VTVT) today announced the completion of enrollment for vTv's Phase 3 placebo-controlled trial, STEADFAST (Single Trial Evaluating Alzheimer's Disease Following Addition to Symptomatic Therapy). STEADFAST is evaluating the efficacy and safety of azeliragon, an oral antagonist of the Receptor for Advanced Glycation Endproducts (RAGE), for treatment of mild Alzheimer's disease.

"To date, vTv is the only company with a clinical stage RAGE program in Alzheimer's disease, and completion of enrollment in this trial marks a significant milestone for the company and an important step forward for the Alzheimer's community," said Steve Holcombe, president and chief executive officer of vTv Therapeutics. "The impact of this disease on patients and their families is devastating. We look forward to sharing results from both trials in 2018 and, if successful, would bring us closer to advancing a new therapy capable of slowing the 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 difference in change from baseline between azeliragon and placebo 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.

STEADFAST, a randomized, double-blind, placebo-controlled Phase 3 trial, is investigating the efficacy of azeliragon as a potential treatment to slow the decline in cognition and functional activities for patients with mild Alzheimer's disease. The 18-month trial targeted enrollment of 800 patients (400 for each Part A and B). Part A enrolled patients in the United States and Canada. Enrollment of Part B included study sites in the United Kingdom, Ireland, Australia, New Zealand and South Africa. Subjects completing the STEADFAST trial are also eligible to enroll in a 24-month open-label extension trial. STEADFAST was conducted following agreement with FDA under the Special Protocol Assessment (SPA) process and the azeliragon development program has been granted fast track designation. Enrollment of Part A was completed in September 2016 with data expected to read out in early 2018 Part B data is expected to read out 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 <u>www.vtvtherapeutics.com</u>.

### **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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