vTv Therapeutics Announces Topline Results from the First STEADFAST Phase 3 Study Evaluating Azeliragon in People with Mild Alzheimer's Disease

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HIGH POINT, N.C.--(BUSINESS WIRE)--Apr. 9, 2018-- vTv Therapeutics, Inc. (vTv) (Nasdaq:VTVT) today announced that results from Part A of the Company's Phase 3 STEADFAST study of the investigational medication azeliragon in people with mild Alzheimer's disease did not meet either co-primary efficacy endpoint. Patients taking azeliragon compared with placebo did not improve in cognitive or functional outcomes as measured by the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) and the Clinical Dementia Rating Scale Sum of Boxes (CDR-sb).

The STEADFAST study is comprised of two independent and identical randomized, double-blind, placebo-controlled Phase 3 trials (Part A and Part B). The azeliragon treated group in Part A had a 4.4 point decline from baseline in ADAS-Cog and a 1.6 point decline from baseline in CDR-sb compared to a placebo decline of 3.3 and 1.6 respectively. These differences were not statistically significant. Azeliragon was generally well-tolerated with a 25% withdrawal rate over 18 months that was similar in both the placebo and treatment arms.

vTv Therapeutics is discontinuing current clinical studies involving azeliragon, including the open-label extension study and Part B of the STEADFAST study. Given the progress to date of STEADFAST Part B, the company expects that a substantial portion of the patients in Part B of STEADFAST will have completed 12 months of treatment under the study protocol. vTv Therapeutics will continue to thoroughly evaluate subset data from Part A and then the dataset from Part B over the coming weeks.

"We will continue to analyze the datasets and trends within subgroups from both Part A and Part B to determine if there are potential benefits or future uses and applications for azeliragon," said Steve Holcombe, chief executive officer, vTv Therapeutics. "On behalf of vTv Therapeutics, we'd like to extend our most sincere and heartfelt gratitude to study participants, their families, physicians and caregivers for their commitment to this important study."

About Azeliragon

vTv Therapeutics 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 may contribute to the pathogenesis of Alzheimer's disease. Azeliragon, also known as TTP488, is conceived as a novel orally active small-molecule antagonist of RAGE.

About STEADFAST

The STEADFAST study, two independent and identical randomized, double-blind, placebo-controlled Phase 3 trials (Part A and Part B), was designed to investigate the safety and efficacy of azeliragon as a potential treatment for patients with mild Alzheimer's disease. The 18-month study targeted enrollment of 800 patients (400 in each trial). The first trial enrolled patients in the United States and Canada who had a clinical diagnosis of mild Alzheimer's disease and an MRI consistent with this diagnosis. Enrollment of the second trial included study sites in the United Kingdom, Ireland, Australia, New Zealand and South Africa.

About vTv Therapeutics

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 Therapeutics has a pipeline of clinical drug candidates for the treatment of Alzheimer's disease, diabetes, inflammatory disorders and the prevention of muscle weakness.

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 clinical programs, 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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