vTv Therapeutics Initiates Phase 2 Clinical Trial Evaluating Azeliragon in Patients with Mild Alzheimer's Disease and Type 2 Diabetes

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HIGH POINT, N.C.--(BUSINESS WIRE)--Jun. 27, 2019-- vTv Therapeutics Inc. (Nasdaq: VTVT) announced today that the first patient has been screened for the phase 2 proof of concept study evaluating the safety and efficacy of azeliragon in patients with mild Alzheimer's disease and type 2 diabetes.

In a post hoc analysis of the phase 3 STEADFAST trial, a subgroup of patients with mild Alzheimer's disease and type 2 diabetes (defined by glycosylated hemoglobin (HbA1c) of greater than 6.5% at any time during the study) who were treated with azeliragon demonstrated a potential benefit in both cognition and function, less brain atrophy and glucose utilization, and decreases in inflammatory biomarkers compared to the same subgroup of patients treated with placebo. Additional details can be found on our publications page.

"We are pleased to announce the initiation of this prospective phase 2 proof of concept study whereby we seek to confirm our findings from the post-hoc analyses of the phase 3 STEADFAST trial," said Steve Holcombe, President and CEO of vTv Therapeutics. "With positive results from this study, we would be able to move quickly into a pivotal phase 3 trial in our pursuit of a treatment to help the millions of people suffering from mild Alzheimer's and type 2 diabetes, two devastating diseases."

This randomized, double-blind, placebo-controlled, multicenter trial consists of sequential phase 2 and phase 3 studies operationally conducted under one protocol. Each part of the study will evaluate the efficacy and safety of azeliragon in patients with mild Alzheimer's disease (screening MMSE 21 to 26, baseline MMSE 19 to 27; and ADAS-cog14 score ≥10) and type 2 diabetes (screening HbA1c 6.5% to 9.5%, inclusive).

The six-month phase 2 study is designed to enroll approximately 100 patients randomized to either azeliragon 5 mg/day or placebo with the primary endpoint of change from baseline at month 6 in ADAS-cog14. The 18-month phase 3 study, to be initiated following top line results from the phase 2 study, is currently designed to enroll approximately 200 patients with co-primary endpoints of change from baseline at month 18 in cognition and function, subject to modification based upon the phase 2 results. More on the study can be found on www.clinicaltrials.gov under the identifier NCT03980730.

vTv expects to report topline results from the phase 2 proof of concept study by the end of the fourth quarter of 2020.

About Azeliragon

Azeliragon, also known as TTP488, is an orally active small-molecule antagonist of the receptor for advanced glycation endproducts, RAGE. 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 ligand interactions lead to sustained inflammatory states that play a role in chronic diseases such as diabetes, inflammation, and Alzheimer's disease.

About vTv Therapeutics

vTv Therapeutics Inc. is a public, 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 diabetes, Alzheimer's disease, and inflammatory disorders.

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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