vTv Therapeutics Announces Topline Results from Part B of Phase 3 STEADFAST Study

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HIGH POINT, N.C.--(BUSINESS WIRE)--Jun. 12, 2018-- vTv Therapeutics Inc. (Nasdaq:VTVT) today announced that results from Part B of the Company's STEADFAST Study of the investigational medication azeliragon in people with mild Alzheimer's disease did not meet co-primary efficacy endpoints. The prespecified subgroup consisted of azeliragon-treated patients with maximal azeliragon plasma concentrations of less than 7.5 ng/mL and baseline Mini Mental State Examination (MMSE) scores between 19 and 27, and the endpoints were statistically significant improvement in cognitive or functional outcomes as measured by the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) and Clinical Dementia Rating Scale Sum of Boxes (CDR-sb) at 12-months compared to placebo.

However, consistent with findings in Part A and the Phase 2b trial, lower maximal plasma concentrations of azeliragon in Part B were associated with improvements in efficacy relative to placebo. For example, when pooling the results of Part A and Part B and comparing change from baseline at 12 months, the azeliragon subgroup (n=88) had a 1.8 point improvement in ADAS-cog, a 0.4 improvement in CDR-sb and a 2.3 improvement in Alzheimer's Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) relative to placebo (n=373).

Relying upon the program's Fast Track Designation status and study results to date, the Company will pursue expedited discussions with the Food and Drug Administration (FDA) to propose a pathway for further clinical development in support of regulatory approval of azeliragon.

"We are eager to obtain early feedback from the FDA based on the results we have achieved and the data that we have observed associating lower plasma levels of the drug and improved efficacy," said Steve Holcombe, chief executive officer, vTv Therapeutics. "As a result, we believe that azeliragon has the potential to address the pressing unmet need in Alzheimer's disease."

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 has a pipeline of clinical drug candidates led by programs for the treatment of Alzheimer's disease and diabetes as well as treatment of inflammatory disorders.

The Company also continues to progress its clinical pipeline of assets for the treatment of diabetes and inflammatory disorders through strategic partnerships, including:

- Conducting a Phase 1b/2 study with vTv's TTP399, a liver selective glucokinase activator in Type 1 diabetics with the Juvenile Diabetes Research Foundation;
- Planning Phase 2/3 clinical trials in China for vTv's TTP273, an oral small molecule GLP-1r agonist, for the treatment of type 2 diabetics in China and other Pacific Rim countries pursuant to a license agreement with Huadong Medicine;
- Advising on Phase 2 clinical development of vTv's HPP737, a selective phosphodiesterase type 4 inhibitor (PDE4) for inflammatory diseases including COPD in China and other Pacific Rim countries pursuant to a license agreement with Newsoara Biopharma Co., Ltd; and
- As part of a worldwide license agreement for development and commercialization with Reneo Pharmaceuticals, monitoring continued development of vTv's HPP593, a selective peroxisome proliferator-activated receptor delta (PPAR-delta) for inflammatory disorders.

About STEADFAST

The STEADFAST study, consisting of 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). Part A enrolled patients in the United States and Canada who had a clinical diagnosis of mild Alzheimer's disease. Part B also enrolled patients at additional study sites in the United Kingdom, Ireland, Australia, New Zealand and South Africa. Clinical trials involving azeliragon, including Part B and the open-label extension, were terminated based on the topline results from Part A showing the trial failed to meet either co-primary endpoint. Further analyses of the Part A data revealed that a sub-population showed benefit relative to placebo at 12 months. That sub-group was pre-specified as the primary population in the SAP submitted to the FDA prior to unblinding Part B.

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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