vTv Therapeutics Presents Baseline Characteristics of the Enrolled Subjects in the Elevage Study Suggesting Comparability to the Post-Hoc Diabetes Subgroup of the Phase 3 STEADFAST Study

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HIGH POINT, N.C., Nov. 04, 2020 (GLOBE NEWSWIRE) -- vTv Therapeutics Inc. (Nasdaq: VTVT) today reported baseline characteristics for the enrolled subjects in the ongoing Elevage clinical study of azeliragon as a potential treatment for mild Alzheimer's disease (AD) in people with type 2 diabetes (NCT03980730). The data demonstrate that the patients enrolled in Elevage (n=43) have similar baseline characteristics to those in the STEADFAST A-study type 2 diabetes (T2D) subgroup (NCT02080364) (n=47). As the company reported in October 2018, data from this subgroup demonstrated nominally significant differences favoring azeliragon compared with placebo on the ADAS-cog11, an instrument used to evaluate cognition. The goal of the Elevage study is to confirm the results of these retrospective analyses in a 6-month Phase 2 study prior to initiating a Phase 3 study.

The Elevage data are being presented today at the 13th Clinical Trials on Alzheimer's Disease (CTAD) Conference - Digital Event, which is being held virtually November 4-7, 2020.

"We have completed enrollment in Part 1 of Elevage and are pleased that the baseline characteristics are consistent with those of the STEADFAST T2D subgroup in which we saw benefit for azeliragon compared with placebo," said Steve Holcombe, President and CEO of vTv Therapeutics. "The Elevage study for azeliragon in this patient population is designed as sequential Phase 2 and 3 trials operationally conducted under one protocol. If the Phase 2 data are positive, this design would allow us to move quickly to a Phase 3 trial with the potential to support product approval. Approximately 35% of patients with AD have T2D, with associated increased advanced glycation endproducts and increased expression of the Receptor for Advanced Glycation Endproducts, the target for azeliragon. We believe that azeliragon could potentially be an important advance for addressing dementia in this population."

Baseline characteristic data presented today demonstrate that the Elevage patient population is similar to that of the STEADFAST T2D subgroup with respect to age, height, weight, body-mass index, ApoE status, background AD medication, HbA1c, and scores on multiple cognitive assessments including Mini-Mental State Exam (MMSE), ADAS-cog11, CDR Global, and CDR Sum of Boxes. The company expects to report topline safety and efficacy data from Part 1 of the Elevage study in December 2020, earlier than previously anticipated.

Details of the CTAD digital presentation are:

Oral Presentation Title: "The Azeliragon Elevage Study: Study Update and Preliminary Data on Baseline Characteristics of Participants with Mild Alzheimer's Disease and Type 2 Diabetes Randomized in Part 1"
Presentation Number: LB5
Category: On Demand, Late Breaking Communications
Date and Time: Wednesday, November 4, 2020, Available from 1 am US EST

About the Elevage Study

The Elevage Study is a randomized, double-blind, placebo-controlled clinical trial evaluating azeliragon in individuals ages 50 – 85 with probable mild-Alzheimer's disease and type 2 diabetes. The objective of the Elevage Study is to replicate in a randomized double-blind, placebo controlled study the results observed in a post hoc analysis of the phase 3 STEADFAST trial A-Study in which a subgroup of forty-seven (47) patients with mild Alzheimer's disease and type 2 diabetes treated with azeliragon demonstrated nominally statistically significant improvements in cognition on the ADAS-cog11 scale of 5.5 points (p=0.006) at month 18 compared to the same subgroup of patients treated with placebo. Azeliragon associated improvement was nominally significant as early as month 6 on the ADAS-cog11 scale (4.9 points, p<0.001).

About vTv Therapeutics
vTv Therapeutics Inc. is a clinical-stage biopharmaceutical company focused on developing oral small molecule drug candidates. vTv has a pipeline of clinical drug candidates led by programs for the treatment of type 1 diabetes, Alzheimer's disease, and inflammatory disorders. vTv's development partners are pursuing additional indications in type 2 diabetes, chronic obstructive pulmonary disease (COPD), and genetic mitochondrial diseases. For more information, please visit www.vtvtherapeutics.com or follow us on Twitter: @vTvTherapeutics.

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.

Contacts

Investors:

Corey Davis
LifeSci Advisors
CDavis@LifeSciAdvisors.com

or

Media:
Glenn Silver
Lazar FINN Partners
646-871-8485
gsilver@lazarpartners.com

Source: vTv Therapeutics Inc.