vTv Therapeutics Presents Positive Data on the Effect of Azeliragon in Patients with Alzheimer's and Diabetes at the 11th Clinical Trials on Alzheimer's Disease (CTAD) Conference

10/24/18

Subgroup Analysis Indicates Potential Benefit of Treatment with Azeliragon for Patients with Type 2 Diabetes and Alzheimer's Disease

Nearly 40 percent of Medicare Beneficiaries with Dementia Also Suffer from Diabetes, a Large Population to Potentially Benefit

HIGH POINT, N.C.--(BUSINESS WIRE)--Oct. 24, 2018-- vTv Therapeutics Inc. (Nasdaq: VTVT), a clinical-stage biopharmaceutical company engaged in the discovery and development of orally administered treatments for Alzheimer's disease (AD) and diabetes, today announced that a subgroup analysis from the azeliragon Phase 3 STEADFAST trial was presented at the 11th Clinical Trials on Alzheimer's Disease (CTAD) conference in Barcelona, Spain. The data presented at the conference included post-hoc, positive data indicating a potential benefit of treatment with azeliragon in AD patients with type 2 diabetes. It is estimated that nearly 40 percent of Medicare beneficiaries age 65 and older with dementia also have diabetes (Alzheimer's Association. 2018 Alzheimer's Disease Facts and Figures).

In a poster presentation titled "Is RAGE the missing link between diabetes and dementia? Results from a subgroup analysis of the STEADFAST trial," researchers from vTv reviewed results from a post-hoc subgroup analysis from the company's STEADFAST trial. This subgroup included 55 patients with type 2 diabetes (defined by glycosylated hemoglobin (HbA1c) of greater than 6.5% at baseline; HbA1c greater than 7.7% was an exclusion criterion at screening) and a clinical diagnosis of Alzheimer's disease in the combined A-Study and B-Study of the STEADFAST trial. The azeliragon-treated group in the A-Study (n=18) demonstrated a 6.1 point benefit on ADAS-cog relative to the placebo group (n=8), which was nominally statistically significant (p = 0.005), and a 1.7 point benefit on CDR-sb relative to placebo (p = 0.08) after 18 months of treatment.

When conducting this subgroup analysis on pooled data from both the A-Study and B-Study and comparing change from baseline at 12 months (B-Study was discontinued at 12 months), the azeliragon subgroup (n=33) demonstrated a 3.5 point benefit on ADAS-cog (p = 0.01) relative to the placebo group (n=22), and a 0.7 point benefit on CDR-sb (p = 0.24) relative to placebo. A copy of the poster can be found on the publications page of the company's website.

"The association between diabetes and dementia is well documented and these findings are supported by the mechanism of action of azeliragon. The Receptor for Advance Glycation Endproducts (RAGE) has been implicated in both the pathogenesis of Alzheimer's disease and diabetic complications. These results, albeit from a smaller number of patients, reinforce this hypothesis and may open a new therapeutic approach for the treatment of not only dementia but also other complications of diabetes," said Carmen Valcarce, Chief Scientific Officer of vTv Therapeutics.

"We are encouraged by the positive benefits experienced by the diabetic patients in this study." said Steve Holcombe, Chief Executive Officer of vTv Therapeutics. "With over 400 million people with diabetes around the world who are at a higher risk of developing dementia, we think these findings warrant further investigation of this therapy for this unmet medical need," added Mr. Holcombe.

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 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.

About STEADFAST

The STEADFAST study, two independent and identical randomized, double-blind, placebo-controlled Phase 3 trials (A-Study and B-Study), 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. While in April and in June 2018 topline results were announced that the A-Study and the B-Study did not meet the co-primary endpoints and clinical trials were ended, subsequent post-hoc subgroup analyses have shown populations that experienced positive benefits.

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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20181024005226/en/

Source: vTv Therapeutics Inc.

vTv Therapeutics Inc.
Investors:
IR@vtvtherapeutics.com
or
Media:
Josh Vlasto, 212-572-5969
PR@vtvtherapeutics.com