vTv Therapeutics Announces Presentation of Phase 2b Azeliragon Results at the 2016 Alzheimer's Association International Conference (AAIC)

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Analysis shows azeliragon 5mg/day resulted in steadily increasing delay in time to cognitive deterioration in mild Alzheimer's disease patients

Azeliragon designed to inhibit RAGE, which affects Aβ accumulation, tau hyperphosphorylation and chronic inflammation

TORONTO--(BUSINESS WIRE)--Jul. 27, 2016-- vTv Therapeutics Inc. (Nasdaq: VTVT), a clinical-stage biopharmaceutical company engaged in the discovery and development of new orally administered treatments for Alzheimer's disease and diabetes, today announced that Phase 2b data with azeliragon in early stage Alzheimer's disease were reviewed in an oral presentation at the 2016 Alzheimer's Association International Conference (AAIC). Data presented show that azeliragon 5mg/day was effective in delaying the time to cognitive deterioration when compared to placebo in patients with mild Alzheimer's disease.

"Azeliragon is the only treatment in advanced development that works by inhibiting RAGE, which is believed to promote Aβ accumulation, tau hyperphosphorylation and chronic inflammation, the leading pathologies in Alzheimer's disease," commented Larry Altstiel, M.D., Ph.D., Chief Medical Officer of vTv Therapeutics. "These highly promising data from our Phase 2b study provide further confidence in azeliragon as a disease-modifying therapy, and support the design of our ongoing pivotal Phase 3 STEADFAST trial in mild Alzheimer's disease."

Results of Responder Analysis

A responder analysis was investigated in the mild disease population (MMSE 21-26) from an 18-month, placebo controlled Phase 2b trial in mild-to-moderate Alzheimer's disease.

The analysis was performed using a cut-point of a 7-point increase in ADAS-Cog_{11} score (an accepted measure of meaningful change in degree of dementia, Vellas et al. 2007) to measure disease progression. For the 7-point cut-point measure, subjects with mild Alzheimer's disease taking 5 mg/day azeliragon had a significant reduction in time-to-progression, with a hazard ratio of 0.5 (log-rank p=0.02) compared with placebo.

As previously reported, subjects with mild-to-moderate Alzheimer's disease in the trial treated with 5mg/day of azeliragon had a mean decreased decline in ADAS-Cog_{11} at 18 months compared to placebo (ADAS-Cog_{11}: 3.1, p=0.008). Patients in the study with mild disease had an even larger benefit in decreasing deterioration in both cognitive outcomes (ADAS-Cog_{11}: 4.0, p=0.018) and functional measures (CDR-sb: 1.0, p= 0.01).

A copy of the presentation will be made available in the **News & Events** section of the Company's website.

About Azeliragon

Azeliragon is a novel orally administered small molecule antagonist of the Receptor for Advanced Glycation Endproducts (RAGE) being evaluated in a pivotal Phase 3 study (STEADFAST). Activation of RAGE is believed to contribute to Alzheimer's disease by promoting an influx of amyloid beta into the brain, increasing hyperphosphorylation of tau, and promoting vascular amyloid deposition and inflammation. By inhibiting RAGE, azelerigon may reduce amyloid beta accumulation, tau hyperphosphorylation and chronic inflammation, three of the principal causes of neuronal damage in Alzheimer's disease.

About the STEADFAST Trial

The Phase 3 STEADFAST trial is a randomized, double-blind, placebo-controlled study evaluating whether azeliragon can effectively slow the cognitive and functional decline of patients with mild Alzheimer's disease (AD). The Company anticipates enrolling 800 patients in the United States and Canada who will receive 18 months of treatment, and expects to report topline data for Part A of the study in late 2017/early 2018. The STEADFAST trial is being conducted under a Special Protocol Assessment (SPA) and the azeliragon development program has been granted Fast Track Designation from the FDA.

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 Type 2 diabetes as well as treatment of 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 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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