



## **vTv Therapeutics Announces Company will Pre-specify New Subgroup with the FDA and Report Phase 3 Part B Results in June**

May 9, 2018

### *Subgroup of Mild Alzheimer's Patients in Part A of Phase 3 STEADFAST Study Demonstrated Positive Benefit*

HIGH POINT, N.C.--(BUSINESS WIRE)--May 9, 2018-- [vTv Therapeutics Inc.](#) (Nasdaq:VTVT) today announced that based on post-hoc analyses of the data from Part A of the Company's Phase 3 STEADFAST study of the investigational medication azeliragon in people with mild Alzheimer's disease, despite not meeting co-primary endpoints, identified a subpopulation that showed statistically significant benefit (unadjusted for multiple, post hoc comparisons) from azeliragon relative to placebo on ADAS-cog. The identified subpopulation consisted of participants with peak azeliragon blood plasma concentration of less than 7.5 ng/mL. Based on the subpopulation data analyses from the Part A study and the prior azeliragon trials, the company will submit a revised Statistical Analysis Plan (SAP) to the Food and Drug Administration for the Part B Study that pre-specifies a target population for the primary study analysis and expects to report Part B topline efficacy results based on 12 month data in June 2018.

The patients in the identified subgroup (n=48) had a -1.9 point improvement in ADAS-cog relative to the placebo group (n=200) which was statistically significant (unadjusted for multiple, post hoc comparisons) ( $p = 0.02$ ), and a 0.5 point improvement on CDR-sb relative to placebo ( $p = .06$ ) despite the smaller sample size. This benefit was observed at 12 months. These findings are consistent with results from an earlier Phase 2b study of azeliragon, in which there was a dose response with improved results in patients who had lower concentrations of azeliragon. In contrast, participants in the Phase 2b and STEADFAST Part A study with high azeliragon concentrations performed worse on the ADAS-cog relative to placebo.

"We are encouraged by the positive improvements in cognitive and functional outcomes relative to placebo based upon low azeliragon concentration levels," said Steve Holcombe, Chief Executive Officer, vTv Therapeutics. "With this understanding, we are continuing to analyze the data and then plan to examine the relevant population prospectively in the Part B study and announce results in June."

Following the April 2018 announcement, the company discontinued clinical trials involving azeliragon, including the Part B study and open label extension. At the time of the closure of the Part B study, a substantial number of participants will have completed 12 months.

### **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 (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). 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. Clinical trials involving azeliragon, including the Part B Study and the open-label extension study have been terminated based on the topline results from the Part A Study showing the trial failed to meet either of the co-primary endpoints. Topline efficacy results from the Part B Study will be announced in June of 2018.

### **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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