vTv Therapeutics Announces Publication in Diabetes Care of Results from SimpliciT-1 Study of TTP399 in Patients with Type 1 Diabetes

February 23, 2021

Results found a clinically meaningful decrease in frequency of severe and symptomatic hypoglycemia in addition to statistically significant reductions in HbA1c

HIGH POINT, N.C., Feb. 23, 2021 (GLOBE NEWSWIRE) -- vTv Therapeutics Inc. (Nasdaq: VTVT), a clinical-stage biopharmaceutical company focused on the development of orally administered treatments for type 1 diabetes (T1D) and inflammatory diseases, today announced that the results from the JDRF-supported SimpliciT-1 Study were published in the American Diabetes Association's Diabetes Care journal. The SimpliciT-1 Study was a multi-center, randomized, double-blind, adaptive study assessing the safety and efficacy of TTP399 as an adjunct to insulin therapy in adults with T1D. TTP399 is a novel, hepatoselective glucokinase activator in development for the reduction of hypoglycemic events in patients with T1D.

The Phase 2 study was conducted in two parts under a treat-to-target protocol to evaluate the safety and efficacy of TTP399 in T1D patients over 12 weeks of daily dosing following a multi-week insulin optimization and placebo run-in period.

Published results from the study showed that treatment with 800mg of TTP399 demonstrated statistically significant reductions in HbA1c, as previously announced. Interestingly, it also resulted in a clinically relevant (~40%) reduction in the frequency of severe or symptomatic hypoglycemia, as compared to placebo. Abnormal serum and urine ketones were detected less frequently in participants in the TTP399 group than in the placebo group. These data suggest the potential of TTP399 to lower HbA1c and reduce hypoglycemia without increasing the risk of ketosis and should be further evaluated as an adjunctive therapy for the treatment of type 1 diabetes. vTv looks forward to initiation of its first pivotal study of TTP399 later this year.

"An adjunctive therapy that protects against the main acute, life-threatening complications of type 1 diabetes while maintaining or improving glycemic control would represent a substantial advancement in clinical standard of care," said Dr. Carmen Valcarce, vTv's chief scientific officer. "The data presented in this publication support our enthusiasm and our commitment to continuing the development of TTP399 as an oral adjunctive therapy to insulin in T1D."

Dr. Klara Klein, MD, PhD, Division of Endocrinology and Metabolism at the University of North Carolina at Chapel Hill, and lead author stated, "The significant improvement in HbA1c, under a stringent treat-to-target design, without an increase in hypoglycemia or blood ketones is a unique observation that, if confirmed in larger studies, reinforces the potential for TTP399 to help people with T1D achieve optimal glycemic control safely."

The publication, titled "The SimpliciT1 study: A randomized, double-blind placebo-controlled, Phase 1b/2 adaptive study of TTP399, a hepatoselective glucokinase activator, for adjunctive treatment of type 1 diabetes mellitus", is published online ahead of print at https://care.diabetesjournals.org/lookup/doi/10.2337/dc20-2684.

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 and inflammatory disorders, including psoriasis. vTv's development partners are pursuing additional indications in type 2 diabetes, chronic obstructive pulmonary disease (COPD), renal disease, and primary mitochondrial myopathy. For more information, please visit https://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:

PR@vtvtherapeutics.com

Source: vTv Therapeutics Inc.

Source: vTv Therapeutics Inc.