vTv Therapeutics Announces Positive Topline Results from Part 1 of the Phase 2 Simplici-T1 Trial in Patients with Type 1 Diabetes

June 6, 2019

TTP399, a novel glucokinase activator shows statistically significant reduction in HbA1c without increases in ketones or hypoglycemia

HIGH POINT, N.C.--(BUSINESS WIRE)--Jun. 6, 2019-- vTv Therapeutics Inc. (Nasdaq: VTVT) today announced positive results from the primary analysis of Part 1 of the Phase 2 Simplici-T1 trial assessing the liver-selective glucokinase activator TTP399 in adult patients with type 1 diabetes (T1D).

In this double-blind, placebo-controlled 12-week trial, the baseline mean HbA1c for the groups treated with TTP399 and placebo was 7.3% and 7.4%, respectively. Patients treated with TTP399 (n=8) showed a statistically significant mean reduction in HbA1c of 0.6% at 12 weeks, while the group treated with placebo (n=11) showed a mean increase in HbA1c of 0.1%, resulting in a mean difference of 0.7% in the TTP399 group relative to the placebo group (p=0.03). At the same time, trends toward decreased insulin usage were observed in the group treated with TTP399.

Patients in this study received insulin adjustments to optimize glucose levels. As a result, the primary analysis included a responder analysis in which a 'treatment responder' was defined as a patient who had a decrease in HbA1c at Week 12, no abnormal lactate or ketones detected in blood or urine during the study, and no increased time in Level 2 hypoglycemia (blood glucose <54 mg/dl). Of all study patients, there was a greater proportion of responders in the group treated with TTP399 (75%) than in the placebo group (9%) (p=0.006). Consistent with the treatment responder results, abnormal ketones were observed in plasma or urine in 63% of patients on placebo vs. 13% of patients treated with TTP399.

TTP399 was well tolerated with similar incidences of treatment-emergent adverse events overall and by system organ class. The study had no serious adverse event reported. The study also had no report of diabetic ketoacidosis or severe hypoglycemia.

"These results from a small group of patients with type 1 diabetes are very exciting. If they hold up in part 2 of the trial, TTP399 will be the most impressive adjunctive therapy to insulin in type 1 diabetes care," said Dr. John Buse, director of the North Carolina Translational and Clinical Sciences Institute and of the Diabetes Center at the University of North Carolina School of Medicine and principal investigator for this study.

More detailed study results will be presented at the 55th Annual Meeting of the European Association for the Study of Diabetes held in Barcelona in September.

"While insulin remains the main line of treatment for T1D, we believe that adjunctive treatments such as TTP399 can lead to improvements in metabolic balance and favorable treatment outcomes for people living with T1D," said Esther Latres, Ph.D., JDRF Director Research. "We are encouraged by the initial results and look forward to critical additional evidence to ascertain the benefits of this therapy and laud the efforts of vTv Therapeutics for their innovative approach to address unmet clinical needs."

"We are excited that TTP399 has demonstrated clinically meaningful efficacy as an adjunct therapy for T1D in this group of patients, and are pleased to have seen a favorable safety profile consistent with what we have seen in our previous trials in patients with type 2 diabetes," said Steve Holcombe, President and CEO of vTv Therapeutics. "Given the well-controlled patient population in this part of the trial, we look forward to the results from part 2 in a broader patient population expected in Q1 2020."

About TTP399
The glucokinase enzyme (GK) is a key regulator of glucose metabolism, and its activation has been shown to increase glucose utilization, which in turn lowers blood glucose. TTP399 is an orally available GK activator that is designed for superior glucose control by targeting GK activation only in the liver with an insulin-independent mechanism of action.

TTP399 has been studied in 12 clinical trials to date, including a 6-month Phase 2b trial in patients with type 2 diabetes where it demonstrated sustained, meaningful reductions in HbA1c and was well-tolerated, with negligible incidences of hypoglycemia and hyperlipidemia, and no occurrences of diabetic ketoacidosis.

About Simplici-T1
Simplici-T1 is a multi-center, randomized, double-blind, adaptive study assessing the pharmacokinetics, pharmacodynamics, safety and tolerability of TTP399 as an adjunct to insulin therapy in adult patients with T1D. The study is being conducted with support from JDRF, the leading global organization funding research in type 1 diabetes.

The Phase 2 learn and confirm study is being conducted in two parts to evaluate the safety and efficacy of TTP399 in T1D patients over twelve weeks of daily dosing. Part 1 enrolled 20 patients on both insulin pumps and CGM's. Part 2 is currently enrolling up to approximately 90 patients using either insulin pumps or multiple daily injection therapy, with CGMs optional.

Enrollment of patients in Part 2 of the study commenced in May 2019 and top line results from the study are expected in the first quarter of 2020.

About Type 1 Diabetes
Type 1 diabetes (T1D) is an autoimmune disease in which a person's pancreas stops producing insulin, a hormone that enables people to get energy from food. It occurs when the body's immune system attacks and destroys the insulin-producing cells in the pancreas, called beta cells. While its causes are not yet entirely understood, scientists believe that both genetic factors and environmental triggers are involved. Its onset has nothing to do with diet or lifestyle. There is nothing you can do to prevent T1D, and—at present—nothing you can do to cure it

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 diabetes, Alzheimer's disease, and inflammatory disorders.

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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Source: vTv Therapeutics Inc.

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