



vTv Therapeutics Presents Two Late-Breaking Poster Sessions on Simplici-T1 Study at the American Diabetes Association's Virtual Sessions Supporting the Potential of TTP399 as First-in-Class Oral Adjunctive Therapy for Type 1 Diabetes Patients

June 13, 2020

- Treatment with TTP399 resulted in significant improvements in HbA1c with reduction in insulin, without increasing risk of hypoglycemia or diabetic ketoacidosis (DKA) -

HIGH POINT, N.C., June 13, 2020 (GLOBE NEWSWIRE) -- [vTv Therapeutics Inc.](http://www.vtvtherapeutics.com) (Nasdaq: VTVT) today made two presentations at the American Diabetes Association's 80th Scientific Sessions. The clinical data presented from the positive Phase 2 Simplici-T1 Study confirms the potential for TTP399 to provide a benefit beyond standalone insulin treatment for patients living with type 1 diabetes.

"These results from the Simplici-T1 Trial are a major step towards the future of care in type 1 diabetes. They demonstrate that TTP399, a once-a-day pill, reduces HbA1c and improves time in range, without increasing hypoglycemia or any signal for adverse events including diabetic ketoacidosis," said John Buse, MD, Director of the North Carolina Translational and Clinical Sciences Institute and of the Diabetes Center at the University of North Carolina School of Medicine. "Despite advances in insulin and type 1 diabetes technologies, affected patients continue to have difficulty achieving optimal glucose control. A safe and effective oral adjunctive therapy would be an important tool for patients and treating endocrinologists to improve both the daily burden of T1D and its long-term outcomes."

A copy of the poster presentations is available on the company website at <http://vtvtherapeutics.com/publications/>.

Details of the presentations follow:

Late Breaking Poster Presentation: [Poster #122-LB](#), The Simplici-T1 Trial: Glucokinase Activator TTP399 Improves Glycemic Control in Patients with Type 1 Diabetes.

Presenter: John Buse, M.D., Ph.D., Director of the North Carolina Translational and Clinical Sciences Institute and of the Diabetes Center at the University of North Carolina School of Medicine

Key results presented included:

- Part 2 of the Simplici-T1 Study confirmed the results from Part 1 in a greater number of subjects (n=85) with TTP399 significantly reducing HbA1c by 0.3% (p<0.01; trial product estimand); 0.2% (p<0.05; FAS), compared to placebo.
- An analysis conducted with treatment responders found a significant difference in the number of responders taking TTP399 (42%) vs. those on placebo (12%) (ITT: p<0.01). Treatment responders were patients that exhibited all of the following: improved HbA1c, no severe or symptomatic hypoglycemia or increase in insulin bolus dose >3U/day, and no abnormal beta-hydroxybutyrate or lactic acid levels.
- Treatment-emergent adverse events were numerically lower in the TTP399 treatment group, with trends towards reduction in hypoglycemic and ketone events in the TTP399-treated group.

Late Breaking Poster Presentation: [Poster #123-LB](#), The Simplici-T1 Trial: Relationship between Glycemic Control and Insulin Dose

Presenter: Carmen Valcarce, Ph.D., Chief Scientific Officer, vTv Therapeutics

Key results presented included:

The treat-to-target (FPG: ~80-130mg/dL; post meal glucose: <180-200 mg/dL) design of the study allowed changes in insulin dose after the insulin-optimization period. To evaluate the effect of these insulin adjustments on HbA1c, several pre-planned analyses were performed grouping the participants according to their change in total insulin doses (decreased, stable or increased).

- Patients randomized to TTP399 achieved better glycemic control (improved HbA1c) while reducing insulin dose. In the placebo-treated group, as expected, reduction in insulin dose was on average associated with a worsening in HbA1c.
- TTP399 significantly reduced HbA1c compared to placebo (0.41%, p=0.01) in patients that decreased their insulin dose or maintained stable insulin dose throughout the study (0.35%, p=0.04).
- Significantly fewer patients in the TTP399 treated group required increases to their insulin dose to maintain their glycemic targets.
- In agreement with the overall analysis, trends towards reduction in hypoglycemic and ketone events were observed in the

TTP399 treated group compared to placebo in the subgroups.

About the Simplici-T1 Study

Simplici-T1 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. The primary endpoint was the change in HbA1c at week 12. The study was conducted with support from JDRF, the leading global organization funding research in type 1 diabetes.

This Phase 2 learn-and-confirm 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. Part 1 enrolled 19 patients on both insulin pumps and CGMs. The positive topline results from the learning phase - Part 1 were reported in [June 2019](#). The confirming phase - Part 2, enrolled 85 patients that used either insulin pumps or multiple daily injections of insulin; CGMs were allowed for those patients using the devices for at least three months prior to the start of the study. The positive topline results from Part 2 of the SimpliciT-1 Study were reported in [February 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 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, Alzheimer's disease, and inflammatory disorders. vTv's development partners are pursuing additional indications in type 2 diabetes, chronic obstructive pulmonary disease (COPD), and genetic mitochondrial diseases.

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.