vTv Therapeutics Presents Additional Positive Clinical Study Results Supporting the Safety and Efficacy of TTP399 as Adjunctive Therapy in Patients with Type 1 Diabetes

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Data Reported at EASD Virtual Conference Demonstrate that TTP399 Did Not Increase Plasma or Urine Ketones, Avoiding a Key Limitation to the Development of Oral Adjunctive Therapies for T1D

HIGH POINT, N.C., Sept. 23, 2020 (GLOBE NEWSWIRE) -- vTv Therapeutics Inc. (Nasdaq: VTVT) yesterday presented data from the completed Phase 2 Simplici-T1 study (NCT03335371) that support the clinical potential of TTP399 as an oral adjunctive therapy in type 1 diabetes (T1D). Newly reported data provide additional evidence suggesting that TTP399 does not increase the risk of diabetic ketoacidosis (DKA), a serious and potentially life-threatening complication that occurs in patients with T1D, due to its unique mechanism of action. DKA is a known side-effect and shortcoming of several investigational oral therapies that have been advanced for T1D, and TTP399's positive impact on ketone levels is a point of important differentiation. The company also presented additional data from the Simplici-T1 study confirming that treatment with TTP399 resulted in significant improvements in HbA1c, with reduction in bolus insulin dose, without increasing the risk of hypoglycemia or DKA.

"The data presented at EASD add to the growing body of evidence supporting the potential of TTP399 to meet the urgent yet still unmet need for an adjunctive therapy for patients living with T1D that improves disease management and health outcomes," said Steve Holcombe, president and CEO of vTv Therapeutics. "The development of adjunctive oral therapies for T1D has been limited by unacceptable rates of hypoglycemia and ketoacidosis, so the absence of these events in the Simplici-T1 study is an important advance not only for vTv Therapeutics but for the T1D research community as a whole. This body of evidence provides a robust foundation on which to initiate our first pivotal study of TTP399, which we expect will commence by the end of 2020."

The data was presented in two oral presentations at the 56th Annual Meeting of the European Association for the Study of Diabetes, which is being held virtually September 21-25, 2020, and are available for download at https://vtvtherapeutics.com/pipeline/ttp399/.

"People with T1D are dependent on insulin for survival, yet are unable to achieve the recommended glycemic targets or avoid long-term complications with current insulin regimens," said Esther Latres, Ph.D., Assistant Vice President of Research at JDRF, which provided funding to support the Simplici-T1 study. "An adjunctive therapy that could enhance glucose control, reduce the need for insulin, and improve long-term health outcomes would transform the lives of individuals living with T1D. We believe that these data support the continued development of TTP399 as an oral adjunctive therapy in this population, and look forward to seeing the results from the planned pivotal trial."

EASD Virtual Presentation Information

Oral Presentation Title: "The Simplici-T1 Trial: Activation of Glucokinase by TTP399 Improves Glycaemic Control in Patients with Type 1 Diabetes"
Presentation Number: 50
Category: OP 09 Novel Agents in Type 1 Diabetes
Date and Time: Tuesday, September 22, 2020, 8:45 AM - 9:00 AM ET

Oral Presentation Title: "Mechanism Matter: Preliminary Evidence That Activation of Glucokinase by TTP399 Does Not Increase Plasma or Urine Ketones in Type 1 Diabetes"
Presentation Number: 51
Category: OP 09 Novel Agents in Type 1 Diabetes
Date and Time: Tuesday, September 22, 2020, 9:00 AM - 9:15 AM ET

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.

About Type 1 Diabetes
Type 1 diabetes 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. For more information, please visit www.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.

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