vTv Therapeutics Presents Additional Positive Data from the Phase 2 Simplici-T1 Study in Patients with Type 1 Diabetes at 55th Annual Meeting of the European Association for the Study of Diabetes

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Patients treated with TTP399 had improved Time in Range (TIR), reduced time in hyperglycemia, fewer hypoglycemic events, and lower bolus insulin dose

HIGH POINT, N.C., Sept. 18, 2019 (GLOBE NEWSWIRE) -- vTv Therapeutics Inc. (Nasdaq: VTVT), today presented additional positive data from its phase 2 Simplici-T1 study in patients with type 1 diabetes (T1D) at the 55th Annual Meeting of the European Association for the Study of Diabetes.

In a poster titled “Results from the sentinel and learning phase of the Simplici-T1 study, the first clinical trial to test activation of glucokinase as an adjunctive treatment for type 1 diabetes”, Dr. Carmen Valcarce, Chief Scientific Officer at vTv Therapeutics presented new continuous glucose monitor (CGM) and insulin dose data from the patients with complete CGM profiles in the completed Phase 2 - Part 1 of the study. Key results presented included:

- TTP399 treatment (n=6) increased Time in Range from baseline to end of treatment by 11% (2.7 hours) (p=0.055) per day (24 hours), and by 12% (1.7 hours) (p=0.04) during the critical waking hours (7am-9pm) relative to placebo (n=9).
- TTP399 treatment reduced the total daily mealtime bolus insulin dose by 23% compared to 4% for placebo while significantly improving glycemic control.
- Patients in the treatment group experienced fewer Level 1 (≥54-70 mg/dl) and Level 2 (<54 mg/dl) hypoglycemic events than patients in the placebo group.

“These new clinical data enhance the very promising topline efficacy results we announced for this part of the study in June, where TTP399 reduced HbA1c levels by 0.7% relative to placebo,” said Steve Holcombe, president and CEO, vTv Therapeutics. “We believe that these results, if confirmed in the larger, on-going portion of the study, would strongly position TTP399 for phase 3 development to help address the needs of patients suffering with T1D.”

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

About the Simplici-T1 Study:

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 19 patients on both insulin pumps and CGMs. The topline results from Phase 2 - Part 1 were reported in June 2019:

- The study met its primary endpoint of change in A1c from baseline after 12 weeks of treatment. Patients treated with TTP399 (n=8) showed a statistically significant mean reduction in HbA1c of 0.7% (p=0.03) at 12 weeks relative to the placebo group (n=11).
- TTP399 was well tolerated with similar incidences of treatment-emergent adverse events overall and by system organ class. The study had neither a serious adverse event nor an incident of diabetic ketoacidosis reported.

Part 2 is now fully-enrolled with patients utilizing a treatment regimen that includes either insulin pumps or multiple daily injection therapy, with CGMs optional. Topline results from the study are expected in the first quarter of 2020.

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 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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