vTv Therapeutics Announces Completion of Phase 1b Study Evaluating TTP399 for the Treatment of Type 1 Diabetes

03/22/18

Simplici-T1 is an adaptive Phase 1b/2 study being conducted with support from JDRF

HIGH POINT, N.C.--(BUSINESS WIRE)--Mar. 22, 2018-- vTv Therapeutics Inc. (Nasdaq: VTVT) today announced the completion of Phase 1b of Simplici-T1, an adaptive Phase 1b/2 study assessing the pharmacokinetics, pharmacodynamics, safety and tolerability of TTP399 in adult patients with type 1 diabetes (T1D). The study, being conducted with support from JDRF, the leading global organization funding T1D research, is designed to evaluate TTP399 as an add-on to insulin therapy for people living with T1D.

The Phase 1b assessment was an open label dose-escalation study in five patients with T1D, designed to determine the tolerability of TTP399 when added to insulin and the appropriate dosing range to be used in Phase 2 of the study. Results showed that TTP399 was found to be well-tolerated and improved or maintained glycemic control while reducing or simplifying an insulin regimen. In a six-month Phase 2b clinical trial of TTP399 in patients with type 2 diabetes, TTP399 demonstrated a statistically significant reduction in HbA1c levels in all TTP399 dose groups compared with placebo. TTP399 was also found to be well-tolerated without increased incidences of hypoglycemia and hyperlipidemia compared to placebo.

“There is a tremendous need for new, safe and effective treatment options for the millions of people living with T1D,” 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. “Maintaining glucose control is imperative for those with T1D and we are optimistic that treatment with TTP399 could potentially offer an improved therapy.”

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. TTP399 exhibits an insulin-independent mechanism of action which may be suitable as an adjunctive treatment for T1D.

“We are pleased that TTP399 continues to show favorable tolerability and hope that further exploration of the therapy in T1D will produce the same positive effects that were evident in previous type 2 diabetes clinical studies,” said Carmen Valcarce, Ph.D., executive vice president, chief scientific officer, vTv Therapeutics. “With support from JDRF and the UNC team, we are excited to initiate the Phase 2 portion of the Simplici-T1 study in April of this year and to further assess the potential of TTP399 as an insulin-adjunctive therapy for T1D to provide superior glucose control than insulin monotherapy.”

About Simplici-T1

Simplici-T1 is a multi-center, randomized, double-blind, adaptive study assessing the pharmacokinetics, pharmacodynamics, safety and tolerability of TTP399 in adult patients with type 1 diabetes (T1D). This study is being conducted in two phases: Phase 1 evaluated the safety of ascending TTP399 dosage regimens each over one week of daily dosing; Phase 2 will evaluate the safety and efficacy of a TTP399 dosing regimen over twelve weeks of daily dosing.

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 Alzheimer’s disease and diabetes as well as treatment of 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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