vTv Therapeutics Initiates Phase 1b/2 Study Evaluating TTP399 for the Treatment of Type 1 Diabetes

November 8, 2017

As Part of Industry Partnership with JDRF

HIGH POINT, N.C.--(BUSINESS WIRE)--Nov. 8, 2017-- vTv Therapeutics Inc. (Nasdaq: VTVT) announced today the initiation of simplici-T1, an adaptive Phase1b/2 study assessing the pharmacokinetics, pharmacodynamics, safety, and tolerability of TTP399 in adult patients with type 1 diabetes (T1D). The study is designed to evaluate whether TTP399 is well tolerated when administered as an add-on to insulin therapy and can improve daily glucose profiles and HbA1c in people living with T1D. Results from the Phase1b part of the study are expected in early 2018. The study is being conducted with support from JDRF, the leading global organization funding type 1 diabetes (T1D) research.

“It is very exciting to launch this effort to potentially develop a completely novel pill therapy for type 1 diabetes,” 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. “This disease is characterized by a huge burden of care on more than one million Americans affected and with limited treatment options. The UNC team is very hopeful that better treatments for type 1 diabetes will be near at hand.”

TTP399 is an orally available glucokinase enzyme (GK) activator that is designed to target GK activation only in the liver for superior glucose control. In the liver, GK is a key regulator of glucose metabolism, and its activation has been shown to increase glucose utilization, which in turn lowers blood glucose. 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.

“We’ve gathered promising data in our clinical studies in type 2 diabetes and are eager to explore the potential of TTP399 as an insulin-adjunctive therapy in type 1 diabetes,” said Carmen Valcarce, Ph.D., executive vice president, chief scientific officer, vTv Therapeutics. “We are in a unique position to develop next-generation therapies with JDRF and the UNC team in our corner, and the simplici-T1 study is a very important stepping stone on the way to reaching our goal to improve the treatment of type 1 diabetes.”

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 Inc.

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 and the prevention of muscle weakness. Last year, vTv announced positive topline results from a placebo and active-comparator-controlled Phase 2b clinical study of TTP399, a liver-selective glucokinase activator under development for the treatment of type 2 diabetes.

The Company’s drug candidates were discovered with its high-throughput drug discovery platform, TTP Translational Technology®, which translates the functional modulation of human proteins into safe and effective medicines. For further company information, visit www.vtvtherapeutics.com.

About JDRF

JDRF is the leading global organization funding type 1 diabetes (T1D) research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. To accomplish this, JDRF has invested more than $2 billion in research funding since our inception. We are an organization built on a grassroots model of people connecting in their local communities, collaborating regionally for efficiency and broader fundraising impact, and uniting on a national stage to pool resources, passion, and energy. We collaborate with academic institutions, policymakers, and corporate and industry partners to develop and deliver a pipeline of innovative therapies to people living with T1D. Our staff and volunteers throughout the United States and our six international affiliates are dedicated to advocacy, community engagement and our vision of a world without T1D. For more information, please visit jdrf.org or follow us on Twitter: @JDRF.

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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