vTv Therapeutics Completes Enrollment of Phase 2b Trial Evaluating TTP399 for the Treatment of Type 2 Diabetes

02/09/16

Oral Glucokinase Activator has potential to address an underlying cause of Type 2 diabetes

Company expects to report topline results in mid-2016

HIGH POINT, N.C.--(BUSINESS WIRE)--Feb. 9, 2016-- vTv Therapeutics Inc. (Nasdaq:VTVT), a clinical-stage biopharmaceutical company engaged in the discovery and development of new orally administered treatments for Alzheimer's disease and diabetes, today announced the completion of patient enrollment in the Company's AGATA (**A**dd **G**lucokinase **A**ctivator to **T**arget **A**1c) study, a Phase 2b clinical trial assessing the efficacy and safety of TTP399 in patients with Type 2 diabetes. TTP399 is a novel oral, liver-selective Glucokinase Activator (GKA) with first-in-class potential.

Data from a previous Phase 2a trial with TTP399 showed the drug significantly lowered blood glucose with no evidence of hypoglycemia, increase in lipids or induction of insulin secretion. Within the high-dose arm of the study, approximately 86% of "well-controlled" patients (A1C levels < 7.5) were able to achieve pre-diabetic A1c levels(<6.5%) after only 6 weeks of treatment without any episodes of hypoglycemia following administration of the oral treatment.

"We are pleased to reach full enrollment of our AGATA study as we continue to make strong progress advancing our novel drug candidates for the treatment of Type 2 diabetes, as well as Alzheimer's," said President and CEO Steve Holcombe. "In earlier clinical studies, TTP399 normalized A1c levels—a measure of glucose—after 6 weeks of treatment without inducing hypoglycemia. Given the large number of patients who are unable to reach their target A1c levels with currently available oral anti-diabetic therapies, we believe TTP399 has the potential to be an important new therapeutic option for sustained glucose control."

Continued Mr. Holcombe, "TTP399 is the first of two diabetes candidates in our pipeline reading out this year. Topline results from the AGATA study will report in the middle of 2016 followed by results from our Phase 2 LOGRA study with TTP273, our oral, small molecule GLP-1R candidate, by the end of 2016."

The AGATA study is a six-month multi-center, double-blind, placebo- and active-controlled, parallel group trial in 180 patients with Type 2 diabetes mellitus on a stable dose of metformin. The primary efficacy endpoint is change in A1c from baseline to the end of randomized treatment. The Company expects to report topline results from this trial in the middle of 2016.

About TTP399

vTv Therapeutics, utilizing its proprietary drug discovery platform, TTP Translational Technology®, has discovered and developed a series of novel, small molecule, liver-selective Glucokinase Activators (GKAs) that appear to stimulate the body's ability to regulate glucose levels without inducing hypoglycemia. TTP399 is the lead clinical candidate and is an oral liver-selective compound with a novel binding mode to glucokinase and physiochemical properties that appear to result in functioning only in the liver without interrupting the physiological regulation of glucokinase by the glucokinase regulatory protein.

In a 6-week, multi-center, Phase 2a study in Type 2 diabetic subjects on stable doses of metformin, TTP399 demonstrated a statistically significant reduction in A1c levels in all TTP399 dose groups compared with placebo, without induction of hypoglycemia or hyperlipidemia and with no induction of insulin secretion in patients with Type 2 diabetes. Within the high-dose arm of TTP399, approximately 86% of patients with A1c levels <= 7.5% at baseline achieved blood glucose normalization, defined as A1c <= 6.5%, after six weeks of treatment, while 50% of patients with A1c levels <= 8.0% at baseline achieved normalization after six weeks. For all doses combined, approximately 40% of patients with A1c levels <= 7.5% at baseline achieved blood glucose normalization while 25% of patients with A1c levels <= 8.0% at baseline achieved normalization. None of the patients receiving placebo reached A1c normalization.

About Type 2 Diabetes

Type 2 diabetes is the body's inability to properly use insulin to control sugar in the bloodstream. It is the most common type of diabetes (representing 90 to 95% of diabetes patients), imposing a growing burden on healthcare systems globally. The goal of maintaining A1c levels below 7.0% is elusive for patients with this life-long disease. In addition to unregulated glucose, diabetics commonly have a variety of co-morbidities, including heart disease, stroke, high blood pressure, blindness, kidney disease, amputations, dental disease, and central and peripheral nervous system impairment.

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 Type 2 diabetes as well as treatment of inflammatory disorders and the prevention of muscle weakness.

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 Registration Statement on Form S-1 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20160209006158/en/

Source: vTv Therapeutics Inc.

For vTv Therapeutics
Investors
The Trout Group
Adam Krop, 646-378-2963
akrop@troutgroup.com
or
Media
BMC Communications
Brad Miles, 646-513-3125
bmiles@bmccommunications.com