

## **vTv Therapeutics Initiates Patient Dosing in the AGATA Study, a six Month Phase 2 Study Evaluating TTP399, a Liver-selective GlucoKinase Activator, for the Treatment of Type 2 Diabetes**

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### ***In a 6 Week Phase 2a Study, Treatment Showed Statistically Significant and Clinically Meaningful Reduction in A1c Levels***

High Point, North Carolina (June 4, 2015)

vTv Therapeutics LLC announced today that it has initiated dosing of the AGATA study, a phase 2b clinical trial assessing the efficacy and safety of TTP399, an oral liver-selective Glucokinase Activator (GKA), in patients with type 2 diabetes. In a phase 2a study, TTP399 demonstrated a statistically significant and clinically meaningful reduction in A1c levels compared with placebo after only 6 weeks of dosing, without induction of hypoglycemia or hyperlipidemia and with no induction of insulin secretion in patients with type 2 diabetes.

The **AGATA** (Add **G**lucokinase **A**ctivator to **T**arget **A1c**) study is a multi-center, double-blind, placebo- and active-controlled (sitagliptin), study to evaluate the safety and efficacy of TTP399 following six months administration in subjects with type 2 diabetes mellitus on a stable dose of metformin. The trial is designed to demonstrate that TTP399 produces significant and sustainable improvement in glycemic control. Patients enrolled will be randomized to receive placebo, 400 mg or 800 mg of TTP399 or 100mg of sitagliptin once daily for a 6 months. The primary efficacy endpoint is change in A1c from baseline to the end of randomized treatment. Key secondary endpoints include changes in lipid parameters and body weight. The AGATA study will be conducted in the United States and is expected to enroll approximately 180 patients.

“Despite the availability of several oral anti-diabetic therapies, a large number of patients with type 2 diabetes do not achieve their recommended A1c target levels. Preclinical and clinical data showed that treatment with TTP399 normalizes A1c without inducing hypoglycemia, therefore convincing us that that TTP399 has the potential to become a new paradigm for the treatment of type 2 diabetes” said Stephen L. Holcombe, President and CEO, vTv Therapeutics LLC. “Glucokinase (GK) is a physiological glucose-sensor. It is a genetically validated target that has been pursued by the industry for years with many failures due to safety issues and loss of efficacy. We have designed TP399 to only activate GK in the liver and not to interrupt the physiological regulation of GK by the GK regulatory protein. The data we have generated with TTP399 suggests this approach to GK activation will bypass the common pitfalls associated with other GKAs and has positioned TTP399 as the leader in GK Activators currently in development”.

### **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 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 GK and physiochemical properties that appear to result in functioning only in the liver without interrupting the physiological regulation of GK by the GK 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  $\leq 7.5\%$  at baseline achieved blood glucose normalization, defined as A1c  $\leq 6.5\%$ , after six weeks of treatment, while 50% of patients with A1c levels  $\leq 8\%$  at baseline achieved normalization after six weeks. For all doses combined, approximately 40% of patients with A1c levels  $\leq 7.5\%$  at baseline achieved blood glucose normalization while 25% of patients with A1c levels  $\leq 8\%$  at baseline achieved normalization. None of the patients receiving placebo reached A1c normalization.

vTv Therapeutics will be presenting pre-clinical data with TTP399 in the following two poster presentations at the 75th American Diabetes Association (ADA)® Scientific Sessions to be held in Boston, Massachusetts from June 5 - 9, 2015:

- **1168-P:** TTP399, a Liver Selective Glucokinase Activator (GKA) that Preserves the Physiological Regulation of Glucokinase (GK) by GK Regulatory Protein (GKRP)
- **1271-P:** TTP399, a Liver Selective Glucokinase Activator, Increases Efficacy of Currently Marketed Therapies for Type 2 Diabetes

### **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 LLC**

vTv Therapeutics LLC 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. vTv's drug candidates were discovered with its high-throughput drug discovery platform, Translational Technology®, which translates the functional modulation of human proteins into safe and effective medicines. For further company information, visit [www.vtvtherapeutics.com](http://www.vtvtherapeutics.com)

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