



vTv Therapeutics Announces Publication in Diabetes Obesity and Metabolism of Complete Results for the Mechanistic Study Assessing Effects of TTP399 on Ketones during Acute Insulin Withdrawal in Patients with Type 1 Diabetes

06/04/22

Results confirmed TTP399 improves glycemia without increasing hypoglycemia and suggest a protective effect of TTP399 against DKA in individuals with T1D

HIGH POINT, N.C., June 04, 2022 (GLOBE NEWSWIRE) -- [vTv Therapeutics Inc.](https://www.vtvtherapeutics.com) (Nasdaq: VTVT), a clinical stage biopharmaceutical company focused on the development of orally administered treatments for type 1 diabetes (T1D), today announced that the results from the JDRF-supported mechanistic study assessing effects of *TTP399* on ketones during acute insulin withdrawal were published in the *Diabetes Obesity and Metabolism* journal and presented at The American Diabetes Association's 82nd Scientific Sessions (#ADA2022) on June 5th.

This Phase 1, mechanistic study evaluated the effects of the GKA *TTP399* on ketoacidosis risk in individuals with T1D on insulin pump therapy. The primary goal was to assess safety of *TTP399* via a primary endpoint of non-inferiority of *TTP399* compared to placebo regarding ketone levels during acute insulin withdrawal (IWT). Indeed, *TTP399* did not alter circulating concentrations of beta-hydroxybutyrate (BOHB) or time to cessation of IWT and confirmed non-inferiority. Pre-specified secondary analyses investigated the potential for benefit. No subject treated with *TTP399* met the prespecified definition of DKA while 42% of placebo-treated subjects met this criterion. Together, these data suggest that *TTP399* does not increase, and may decrease, the risk of diabetic ketoacidosis (DKA) in subjects with T1D.

This finding stands in direct contrast to other promising oral adjunctive therapies tested in T1D. During similar insulin withdrawal experiments, SGLT2i use significantly increased ketonemia in people with T1D during insulin withdrawal¹. Moreover, off-label use of SGLT2i in the real world is associated with substantially increased risk of euglycemic DKA². That *TTP399* did not result in increased BOHB during acute insulin withdrawal and instead demonstrated a trend toward lowering risk of metabolic acidosis suggests that *TTP399* will not increase the risk of DKA when used in the real world.

The data from this study support prior studies that demonstrate that *TTP399* improves glucose control and reduces hypoglycemia and suggest a protective effect of *TTP399* against acidosis in people with T1D.

"There is an urgent need to develop adjunctive therapies to improve metabolic control in people with type 1 diabetes," said Jonathan Rosen, JDRF Associate Director of Research. "This mechanistic study showing that *TTP399* did not raise ketone levels relative to placebo adds to the body of data arguing that vTv's liver-selective glucokinase activator has promise to be a safe, effective therapy for type 1 diabetes."

The publication, titled "Impact of the Hepatoselective Glucokinase Activator TTP399 on Ketoacidosis During Insulin Withdrawal in People with Type 1 Diabetes," will be available online ahead of print on June 4th at 10am CDT at:

<https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.14697>

¹ Herring et al, Diabetes Care 2020 <https://doi.org/10.2337/dc19-2579>

² Peters et al, Diabetes Care. 2015 <https://doi.org/10.2337/dc15-0843>

About TTP399

TTP399 is a novel, oral, small molecule, liver selective glucokinase activator being developed as an adjunct therapy to insulin in patients with type 1 diabetes. In a recent phase 2 clinical trial, *TTP399* showed a 40% reduction in hypoglycemic episodes compared to placebo. In April 2021, the FDA granted Breakthrough Therapy designation to *TTP399* for the treatment of type 1 diabetes. This past October, vTv announced results of a mechanistic study of *TTP399* in patients with type 1 diabetes demonstrating no increased risk of ketoacidosis. *TTP399* has now been tested in almost 600 subjects. *TTP399* is still in the development phase; the FDA has not reviewed or approved *TTP399* for use in the United States.

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 type 1 diabetes and cystic fibrosis related diabetes. vTv's development partners are pursuing additional indications in type 2 diabetes, chronic obstructive pulmonary disease, renal disease, primary mitochondrial myopathy, and pancreatic cancer.

For more information, please visit www.vtvtherapeutics.com.

Forward-Looking Statements

This release contains forward-looking statements, which involve risks and uncertainties, including statements regarding the potential grant of the FDA

Approval. 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 agreements and transactions described in this release are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors, including the risk that the FDA Approval is not received on a timely basis or at all, 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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