



vTv Therapeutics Announces Screening of First Patient in CATT1 Pivotal Trial Evaluating Cadisegliatin for Type 1 Diabetes

June 24, 2024 at 4:05 PM EDT

Cadisegliatin is a potential first-in-class oral liver selective glucokinase activator for T1D, which has been granted Breakthrough Therapy designation by the FDA for T1D

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HIGH POINT, N.C., June 24, 2024 (GLOBE NEWSWIRE) -- vTv Therapeutics Inc. (Nasdaq: VTVT), a late stage biopharmaceutical company with an innovative clinical portfolio of small molecules and lead program in diabetes, today announced that the first patient has been screened in the Company's [CATT1 pivotal trial](#) evaluating *cadisegliatin* as an adjunct treatment of type 1 diabetes (T1D). CATT1 is designed to be a registrational study and is one of several trials that will form the core of the regulatory submission for *cadisegliatin*, a potential first-in-class, oral, liver selective, glucokinase activator for T1D that has been dosed in over 500 subjects to date, including 300 patients with T1D and type 2 diabetes (T2D).

"Maintaining glycemic control remains a high and burdensome unmet need for the nearly 8 million people with T1D worldwide. *Cadisegliatin* is a new approach to current standards of care that is designed to regulate blood glucose levels by selectively activating glucose pathways in the liver," said Paul Sekhri, Chairman, President and Chief Executive Officer of vTv Therapeutics. "Screening the first patient marks an important milestone for our late stage *cadisegliatin* program and brings us closer to our mission of delivering novel treatments that help improve the lives of millions of patients living with diabetes."

Dr. Thomas Strack, Chief Medical Officer of vTv Therapeutics added, "85% of patients with T1D experience one or two hypoglycemic episodes every week, representing an important barrier that limits optimal treatment. *Cadisegliatin* is designed to reactivate the glucose-regulating capacity in the liver independent of insulin to safely improve episodes of hyper- and hypoglycemia in patients with diabetes."

CATT1 is a randomized, double-blind, placebo-controlled pivotal study evaluating the efficacy and safety of *cadisegliatin* over 12 months in adults 18 years or older diagnosed with T1D. The trial is expected to enroll approximately 150 patients at up to 20 sites in the U.S. Two doses of orally administered *cadisegliatin* versus placebo will be assessed in patients currently being treated with multiple daily insulin injections and continuous subcutaneous insulin infusion who use a continuous glucose monitor. The primary efficacy endpoint of the study will compare the incidence of Level 2 or Level 3 hypoglycemic events between *cadisegliatin*-treated subjects and those in the placebo group.

Cadisegliatin will also be evaluated as an adjunctive therapy to insulin in patients with T2D as part of a planned Phase 2 trial in Middle Eastern countries in collaboration with G42 Healthcare Research Technology Projects LLC and its clinical research organization IROS, a UAE-based health technology group which is expected to start in the second half of 2024.

About Cadisegliatin

Cadisegliatin (TTP399) is a novel, oral small molecule, liver selective glucokinase activator with first-in-class potential as an adjunct treatment for type 1 diabetes (T1D). Selectively acting on the liver, *cadisegliatin* increases the activity of glucokinase independently from insulin to improve glycemic control through hepatic glucose uptake and glycogen storage.

About vTv Therapeutics

vTv Therapeutics Inc. is a late stage biopharmaceutical company focused on developing oral, small molecule drug candidates. vTv's clinical pipeline is led by *cadisegliatin*, a potential adjunctive therapy to insulin for the treatment of type 1 diabetes. vTv and its development partners are pursuing additional indications including type 2 diabetes and other chronic conditions.

Forward-Looking Statement

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.

Contact

Ashley Robinson

LifeSci Advisors, LLC

arr@lifesciadvisors.com



Source: vTv Therapeutics Inc.