vTv Therapeutics Announces First Study Participant Randomized in CATT1 Phase 3 Trial of Cadisegliatin in Type 1 Diabetes

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Topline results from CATT1 Phase 3 trial expected in second half of 2026

HIGH POINT, N.C., Aug. 07, 2025 (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 the first study participant has been randomized in the Company's CATT1 Phase 3 trial investigating *cadisegliatin* as an adjunctive treatment to insulin in adults with type 1 diabetes (T1D). *Cadisegliatin* is a potential first-in-class, oral, liver-selective glucokinase activator for T1D that has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) and has been well-tolerated in over 500 subjects to date with up to six months of treatment.

Despite major advances made in medical devices used to help manage blood glucose levels in people living with T1D, there have been few therapeutic advances. To date, there has not been any FDA-approved oral adjunct therapy to insulin to treat T1D. "Randomizing the first participant in CATT1 represents another key milestone for vTv's development of *cadisegliatin* as a potential therapy to improve glycemic control for the nearly 1.6 million Americans living with T1D," said Dr. Thomas Strack, Chief Medical Officer of vTv Therapeutics. "We look forward to reporting topline Phase 3 data from CATT1 in the second half of 2026."

The Phase 3 CATT1 trial (NCT06334133) is being conducted at up to 25 sites in the U.S. Recruitment is ongoing, and the trial is expected to enroll approximately 150 participants. The trial is a randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of *cadisegliatin* over six months in adults 18 years or older diagnosed with T1D. Two different dose regimens (800 mg once or twice daily) of orally administered *cadisegliatin* versus placebo will be assessed in participants currently being treated with multiple daily insulin injections or continuous subcutaneous insulin infusion. Per the protocol, continuous glucose monitors (CGM) will now be provided to all participants to inform the primary study endpoint, which is the incidence of level 2 and 3 hypoglycemic events in *cadisegliatin*-treated participants compared to those in the placebo group (insulin alone). Select secondary endpoints include reduction in hemoglobin A1C (HbA1c), time in target range of glycemic control, and incidence of diabetic ketoacidosis.

"Although there have been major advances in medical devices for the treatment of type 1 diabetes, there is a huge unmet need to identify therapies that improve glycemia without increasing the risk of ketosis or hypoglycemia," said diabetes expert, Klara Klein, MD, PhD, who is Assistant Professor of Medicine at the University of North Carolina at Chapel Hill. "People with type 1 diabetes continue to walk a tightrope between hyper- and hypoglycemia. There's real potential for glucokinase activators not only to improve glycemia overall but to do so while providing some protection against hypoglycemia and, potentially, diabetic ketoacidosis, which could ease some of the mental burden of type 1 diabetes care."

About Cadisegliatin

Cadisegliatin (TTP399) is a novel, oral small molecule, liver-selective glucokinase activator being investigated as a potential first-in-class oral adjunctive treatment for type 1 diabetes (T1D). In non-clinical studies, *cadisegliatin,* acting selectively on the liver, increased the activity of glucokinase independently from insulin which supports clinical investigation of improvement in glycemic control through hepatic glucose uptake and glycogen storage.

Cadisegliatin is under investigation and the safety and efficacy have not been established. There is no guarantee that this product will receive health authority approval or become commercially available for the use being investigated.

About vTv Therapeutics

vTv Therapeutics is a late-stage biopharmaceutical company focused on developing oral, small molecule drug candidates intended to help treat people living with diabetes and other chronic diseases. vTv's clinical pipeline is led by *cadisegliatin*, currently in a Phase 3 trial, a potential first-in-class oral glucokinase activator being investigated for the treatment of type 1 diabetes. vTv and its development partners are investigating multiple molecules across different indications for chronic diseases. Learn more at vtvtherapeutics.com or follow the company on LinkedIn or X.

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 our forward-looking statements by these cautionary statements.

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