



vTv Therapeutics Announces Reinitiation of Screening in CATT1 Phase 3 Trial Evaluating Potential First-in-Class Liver-Selective Glucokinase Activator Cadisegliatin for Type 1 Diabetes

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Topline CATT1 Phase 3 data is expected in 2H 2026

Protocol amendment shortens trial duration from 12 to 6 months, expediting time to topline data

HIGH POINT, N.C., May 15, 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 that screening has been reinitiated in the Company's CATT1 Phase 3 trial investigating *cadisegliatin* as an adjunctive treatment of 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 Food and Drug Administration (FDA).

"We are thrilled that we have resumed our CATT1 Phase 3 trial and screened a subject under the amended protocol," said Paul Sekhri, Chairman, President and Chief Executive Officer of vTv Therapeutics. "The amendment to the protocol will help expedite time to both topline data and the initiation of required larger pivotal studies moving us one step closer to the future New Drug Application (NDA) submission. We look forward to reporting topline Phase 3 data from CATT1 in the second half of 2026."

vTv Therapeutics reinitiated the CATT1 study and has screened a subject under a recently submitted protocol amendment that reduced the overall duration of the trial from 12 to 6 months, which will expedite time to topline data with no impact on the key study endpoints. Under the protocol amendment, continuous glucose monitors (CGM) will now be provided to all participants to inform the primary study endpoint, which is the number of level 2 and level 3 hypoglycemic events.

CATT1 is a randomized, double-blind, placebo-controlled Phase 3 study evaluating the efficacy and safety of *cadisegliatin* over 6 months in adults 18 years or older diagnosed with T1D. The trial is expected to enroll approximately 150 patients at 20-25 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 provided continuous glucose monitor. The primary efficacy endpoint of the study will compare the incidence of level 2 and level 3 hypoglycemic events between *cadisegliatin*-treated subjects and those in the placebo group.

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 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 being investigated 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 our forward-looking statements by these cautionary statements.

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