vTv Therapeutics Announces FDA has Lifted Clinical Hold on Cadisegliatin Program for Diabetes

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Cadisegliatin has the potential to be the first oral adjunct therapy for type 1 diabetes

CATT1 Phase 3 trial expected to resume following submission of protocol amendment shortening the overall duration of the trial from 12 to 6 months

HIGH POINT, N.C., March 17, 2025 (GLOBE NEWSWIRE) -- vTv Therapeutics Inc. (Nasdaq: VTVT), a clinical stage biopharmaceutical company focused on the development of *cadisegliatin*, a potential first-in-class oral adjunctive therapy to insulin being investigated for the treatment of type 1 diabetes (T1D), today announced that the United States Food and Drug Administration (FDA) has lifted the clinical hold on the c*adisegliatin* clinical program, which includes the CATT1 Phase 3 trial in type 1 diabetes (T1D). *Cadisegliatin* is an oral, liver-selective glucokinase activator that has been generally well tolerated in over 500 subjects to date with up to six months of treatment.

vTv Therapeutics expects to resume the trial following submission of a protocol amendment to reduce the overall duration of the CATT1 trial from 12 months to 6 months, which will help to expedite the initiation of required larger pivotal studies for future New Drug Application (NDA) submission. The original primary endpoint of ascertaining level 2 and 3 hypoglycemia rates at 6 months will not change. The planned amendment will not include the additional 6-month period to collect safety data. By shortening the trial from 12 to 6 months, the Company will be able to obtain topline data from the study more quickly.

"We are pleased that the FDA has lifted the clinical hold on our c*adisegliatin* program and are eager to resume our Phase 3 trial. Importantly, we plan to submit a protocol amendment to reduce the time to topline data by 6-months, which will allow us to initiate our larger Phase 3 studies sooner to support our future NDA submission," said Paul Sekhri, Chairman, President and Chief Executive Officer of vTv Therapeutics. "*Cadisegliatin* has the potential to be the first oral adjunctive therapy to insulin for T1D and we look forward to further evaluating the effects of *cadisegliatin* on glycemic control and incidence of hypoglycemia over insulin alone after reinitiating the CATT1 Phase 3 trial."

On July 26, 2024, vTv Therapeutics announced a clinical hold on the CATT1 Phase 3 trial based on the discovery of a chromatographic signal in a human absorption, distribution, metabolism, and excretion (ADME) study of *cadisegliatin* that could not be resolved by standard mass spectroscopy. No patient had been dosed in the CATT1 trial at the time of the clinical hold, and past clinical studies did not reveal any clinically concerning safety issues. The clinical hold was lifted as of March 14, 2025, following submission of a complete response letter by vTv Therapeutics which concluded that the chromatographic signal was an experimental artifact.

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 to insulin for type 1 diabetes (T1D). In nonclinical 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 novel oral, small molecule drug candidates intended to help treat millions with chronic diseases. vTv's clinical pipeline is led by *cadisegliatin*, a potential first-in-class oral adjunctive therapy to insulin being investigated for the treatment of type 1 diabetes.

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.

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