vTv Therapeutics Announces FDA Submission for First Phase 3 Study of Cadisegliatin in Patients with Type 1 Diabetes

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HIGH POINT, N.C., March 04, 2024 (GLOBE NEWSWIRE) -- vTv Therapeutics Inc. (Nasdaq: VTVT), a clinical stage biopharmaceutical company focused on the development of *cadisegliatin* (TTP399) as an adjunctive therapy to insulin for the treatment of type 1 diabetes ("T1D"), today announced the submission of the study protocol to the FDA for the Company's first Phase 3 trial evaluating the safety and efficacy of its lead candidate, *cadisegliatin*, in adults diagnosed with T1D.

This randomized, double-blind, placebo-controlled trial is expected to enroll approximately 150 patients at up to 20 sites in the United States, with the first patient expected to be enrolled in the second quarter of 2024.

The Phase 3 study will assess two doses of orally administered *cadisegliatin* versus placebo in patients currently being treated with multiple daily insulin injections and continuous subcutaneous insulin infusion, who use a continuous glucose monitor (CGM). 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.

This trial further expands vTv's research into *cadisegliatin* as an adjunctive therapy to insulin, which also includes a planned Phase 2 trial in patients with type 2 diabetes expected to start in Middle Eastern countries in 2024 in collaboration with vTv's partner G42 Healthcare Research Technology Projects LLC and its clinical research organization IROS, a UAE-based health technology group.

"vTv's primary focus is on expeditiously confirming the safety and efficacy of *cadisegliatin*, and this initial Phase 3 trial will help provide a more robust body of clinical evidence on the drug's profile in a relatively short timeframe. The ongoing support from institutional investors who participated in our recent private placement reflects the urgent need for treatments that improve glycemic control and have a positive impact on the quality of life of patients with T1D," said Thomas Strack, MD, PhD, Chief Medical Officer, vTv Therapeutics.

Cadisegliatin is not yet licensed or approved anywhere globally and has not been demonstrated to be safe or effective for any use.

About *Cadisegliatin*

Cadisegliatin (TTP399) is an investigational liver-selective glucokinase activator that has been studied in healthy volunteers and in patients with type 1 and type 2 diabetes.

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 *cadisegliatin* (TTP399), 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 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. In addition, we may not be able to successfully complete a successful financing, partnering or licensing transactions with respect to *cadisegliatin*. 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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