



vTv Therapeutics and M42's IROS Announce Submission of Phase 2 Clinical Study Protocol for Cadisegliatin in Type 2 Diabetes to the United Arab Emirates Department of Health

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Trial to assess cadisegliatin as potential adjunctive therapy to insulin in patients with T2D

HIGH POINT, N.C., Dec. 18, 2025 (GLOBE NEWSWIRE) -- vTv Therapeutics Inc. (Nasdaq: VTVT), a late-stage biopharmaceutical company, today announced a Phase 2 clinical study protocol developed in collaboration with M42's Insights Research Organization & Solutions (IROS), a leading United Arab Emirates (UAE)-based contract research organization, has been submitted to the Department of Health (DOH) Abu Dhabi. The study is designed to evaluate the safety and efficacy of *cadisegliatin*, a potential first-in-class oral adjunctive therapy to insulin, in people living with type 2 diabetes. This study constitutes the longest trial investigating *cadisegliatin* to date and will be a 12-month, double-blind, randomized, placebo-controlled trial enrolling approximately 300 patients with type 2 diabetes who are treated with insulin for glycemic control. Participants will be randomized into three arms: two *cadisegliatin* dose groups (400 mg and 800 mg once daily) and a placebo control group. The trial will take place in the UAE, Jordan, and Tunisia, with the first patient first visit expected in the first quarter of 2026.

"Through our collaboration with M42, we continue to investigate *cadisegliatin*'s potential as an adjunctive therapy to insulin for people living with diabetes," said Paul Sekhri, Chairman, President, and CEO of vTv Therapeutics. "This study also expands the potential geographic footprint for *cadisegliatin*."

"The launch of this trial enables us to evaluate the safety and efficacy of *cadisegliatin* over the course of one year in people with insulin-dependent type 2 diabetes, allowing for extended observation of the impact of our investigational oral adjunctive therapy," said Thomas Strack, MD, Chief Medical Officer of vTv Therapeutics.

"Collaborating with vTv Therapeutics on this Phase 2 study positions us to explore opportunities to potentially impact the lives of millions of people with type 2 diabetes who are not currently able to maintain glycemic control," said Islam Altantawy, General Manager at IROS. "Given that the prevalence of type 2 diabetes among UAE nationals is among the highest globally, we see potential for *cadisegliatin* to assist in glucose management efforts in this population."

As part of the collaboration between vTv and M42, vTv is the regulatory sponsor of the trial and M42 is funding the study.

About Cadisegliatin

Cadisegliatin (TTP399) is a novel, oral small molecule, liver-selective glucokinase activator being investigated in the US 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* has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA).

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 US 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](#).

About IROS

IROS, part of the M42 group, a global tech-enabled health powerhouse, is a pioneering UAE-based Clinical Research Organization (CRO) dedicated to advancing excellence in clinical research and real-world evidence. Its mission is to leverage cutting-edge technologies to innovate in health and drive breakthroughs in clinical research. By conducting high-quality research and achieving groundbreaking insights, IROS aims to improve patients' lives and shape the health landscape.

IROS' comprehensive offerings span all therapeutic domains, positioning it as a leader in regional medical research. With a team of high-caliber experts committed to precision, IROS offers both full-service solutions and tailored services to meet the unique needs of its partners. The organization continually integrates the latest technologies and techniques to drive innovation and excellence.

For more information, please visit, <https://iros.ai>

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 satisfaction of the closing conditions set forth in the securities purchase agreement, the expected use of proceeds from the offering, the timing of our clinical trials, the anticipated effect of Phase 3 topline data on the Company, the benefits of *cadisegliatin* to people living with T1D, 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, subsequent Quarterly Reports on Form 10-Q 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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