



vTv Therapeutics Announces FDA Orphan Drug Designation for HPPD in Sickle Cell Disease

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Milestone supports partnering discussions for HPPD as the Company continues to prioritize its lead late-stage type 1 diabetes (T1D) program, cadisegliatin

HIGH POINT, N.C., Oct. 07, 2026 (GLOBE NEWSWIRE) -- vTv Therapeutics Inc. (Nasdaq: VTVT), a late-stage biopharmaceutical company advancing cadisegliatin, a novel oral investigational therapy for type 1 diabetes (T1D), today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to HPPD, the Company's oral, first-in-class Nrf2/Bach1 modulator. HPPD is being investigated as a treatment for sickle cell disease.

"The FDA's Orphan Drug Designation reinforces both the urgency of the unmet need in this devastating disease and the opportunity to bring forward potential new therapeutic approaches," said Paul Sekhri, Chairman, President, and CEO of vTv Therapeutics. "Receiving this designation marks an important inflection point for this program and strengthens vTv's ability to advance strategic partnering discussions for HPPD while continuing to develop cadisegliatin in T1D."

Preclinical studies conducted at Augusta University using the Townes sickle cell disease mouse model showed that HPPD was orally active and well tolerated, increased fetal hemoglobin, and reduced oxidative stress and red blood cell sickling. These findings support the continued development of HPPD in sickle cell disease.

About Sickle Cell Disease

Sickle cell disease is a lifelong, inherited blood disease characterized by chronic hemolytic anemia, recurrent vaso-occlusive pain crises, oxidative stress, progressive organ damage, and reduced quality of life. It affects approximately 100,000 people in the United States; more than 90% are non-Hispanic Black or African American, and an estimated 3-9% are Hispanic or Latino.ⁱ Although induction of fetal hemoglobin (HbF) remains a validated disease-modifying strategy and hydroxyurea is an important, approved HbF-inducing therapy, many patients continue to face inadequate response, tolerability challenges, or persistent complications.ⁱⁱ These ongoing gaps show the need for additional oral therapies with novel mechanisms of action that may help address the underlying biology of sickle cell disease.

About HPPD

HPPD (HPP8668) is an investigational, oral, first-in-class Nrf2/Bach1 modulator being developed by vTv Therapeutics for the treatment of sickle cell disease. Preclinical studies in the Townes sickle cell disease mouse model have shown that HPPD induces fetal hemoglobin (HbF) in a time- and dose-dependent manner, with effects comparable to or exceeding hydroxy urea, the current standard HbF-inducing therapy. In addition to HbF induction, HPPD showed reductions in oxidative stress and sickled red blood cells, supporting its potential as a disease-modifying oral therapy with a differentiated mechanism of action. HPPD is under investigation, and 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 Cadisegliatin

Cadisegliatin (TTP399) is a novel, oral small-molecule, glucokinase activator being investigated in the U.S. as a potential first-in-class adjunctive treatment for T1D. In nonclinical studies, cadisegliatin acted selectively on the liver and increased the activity of glucokinase independently of insulin. These studies support clinical investigation of whether cadisegliatin can improve 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 its 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, a potential first-in-class oral glucokinase activator being investigated in a U.S. Phase 3 study for the treatment of T1D. 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](#).

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 variations or comparable terminology. All statements other than statements of historical facts contained in this release, including statements regarding 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, mergers, dispositions, joint ventures, or investments we may undertake. We qualify all our forward-looking statements by these cautionary statements.

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ⁱ <https://www.cdc.gov/sickle-cell/data/index.html>

ⁱⁱ Platt OS. *Hydroxyurea for the Treatment of Sickle Cell Anemia*. New England Journal of Medicine. 2008;358:1362-1369.

