



vTv Therapeutics Receives FDA Breakthrough Therapy Designation for TTP399 for the Treatment of Type 1 Diabetes

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Designation offers potential for expedited development pathway and reinforces TTP399's potential to provide a substantial clinical benefit

HIGH POINT, N.C., April 13, 2021 (GLOBE NEWSWIRE) -- [vTv Therapeutics Inc.](#) (Nasdaq: VTVT) a clinical-stage biopharmaceutical company focused on the development of orally administered treatments for type 1 diabetes and psoriasis, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for TTP399 as an adjunctive therapy to insulin for the treatment of type 1 diabetes. TTP399 is a novel, oral, investigational once-daily glucokinase activator.

Breakthrough Therapy designation is based on FDA's determination that preliminary clinical evidence indicates that an investigational therapy may demonstrate substantial improvement on one or more significant endpoints relative to available therapies for a serious or life-threatening condition. Once granted, Breakthrough Therapy designation provides a sponsor with added support and the potential to expedite development and review timelines for a promising new investigational medicine. The Breakthrough Therapy designation for TTP399 in type 1 diabetes was supported by the recent positive results from the phase 2 Simplicit-1 Study, a multi-center, randomized, double-blind, adaptive study assessing the safety and efficacy of TTP399 as an adjunct to insulin therapy in adults with type 1 diabetes. In this trial, treatment with TTP399 resulted in a statistically significant improvement in HbA1c relative to placebo and a clinically meaningful decrease (40%) in the frequency of severe and symptomatic hypoglycemia. TTP399 demonstrated a favorable safety profile, with abnormal levels of serum or urine ketones detected less frequently in patients taking TTP399 than those taking placebo.

"This FDA Breakthrough Therapy designation is an important milestone in the development of TTP399 for the treatment of type 1 diabetes, a serious, life threatening, and life-long condition impacting the day-to-day lives of more than a million Americans," said Steve Holcombe, chief executive officer of vTv. "Hypoglycemia remains a leading cause of morbidity and potential mortality in the treatment of type 1 diabetes. Patient and prescriber fear of hypoglycemia often precludes tight glycemic control and this FDA designation highlights the potential of TTP399 to address this serious unmet medical need. We look forward to working with the FDA as we advance the development of TTP399, and in particular as we begin pivotal trials later this year."

About FDA Breakthrough Therapy Designation

Breakthrough Therapy designation is granted by the FDA in order to expedite the development and review of drugs for serious or life-threatening conditions. In order to receive Breakthrough Therapy designation, a drug must demonstrate preliminary clinical evidence that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. Breakthrough Therapy designation provides an organizational commitment involving senior managers from the FDA, more intensive FDA guidance on an efficient drug development program, and greater access to and more frequent communication with the FDA throughout the entire drug development and review process. It also provides the opportunity to submit sections of a New Drug Application on a rolling basis, where the FDA may review portions of the application as they are received instead of waiting for the entire submission. In addition, Breakthrough Therapy designated products are eligible for Priority Review, where the FDA has a goal to take action on an application within six months, as opposed to ten months under standard review. Breakthrough Therapy designation does not change the standards for approval.

About Type 1 Diabetes

Type 1 diabetes is an autoimmune disease in which a person's pancreas stops producing insulin, a hormone that enables people to get energy from food. It occurs when the body's immune system attacks and destroys the insulin-producing cells in the pancreas, called beta cells. While its causes are not yet entirely understood, scientists believe that both genetic factors and environmental triggers are involved. Its onset has nothing to do with diet or lifestyle. There is nothing you can do to prevent type 1 diabetes, and—at present—nothing you can do to cure it.

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 programs for the treatment of type 1 diabetes and psoriasis. vTv's development partners are pursuing additional indications in type 2 diabetes, chronic obstructive pulmonary disease, renal disease, and primary mitochondrial myopathy. For more information, please visit www.vtvtherapeutics.com or follow us on Twitter: @vTvTherapeutics.

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. 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.

Contacts

Investors:

Corey Davis
LifeSci Advisors
CDavis@LifeSciAdvisors.com

or

Media:

PR@vtvtherapeutics.com



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