vTv Therapeutics Announces Results of Multiple Ascending Dose Study and Development Plan for HPP737, an Oral PDE4 Inhibitor for the Treatment of Psoriasis

September 23, 2021

HPP737 exhibited favorable safety and tolerability profile, with no dose limiting gastrointestinal side effects

Results build on data from previous multiple ascending dose study and support advancement of HPP737 into Phase 2 in moderate to severe psoriasis.

Successful pre-IND meeting with U.S. Food and Drug Administration Division of Dermatology and Dentistry supports planned IND submission for a Phase 2 study in moderate to severe psoriasis.

HIGH POINT, N.C., Sept. 23, 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 results of a multiple ascending dose study evaluating HPP737, an orally administered phosphodiesterase type 4 ("PDE4") inhibitor, in healthy adults. The trial enrolled 12 subjects in each of two dose cohorts, 15mg and 20mg, randomized to receive HPP737 or placebo (3:1) orally once daily for 14 days. Dose escalation up to 20mg/day demonstrated approximate dose proportional increases in exposure, while maintaining a favorable safety and tolerability profile with no dose limiting safety or tolerability findings observed. There were no serious adverse events and no discontinuations due to treatment emergent adverse events. vTv therefore believes that the current safety profile allows it to move forward in development with a drug that may achieve anti-inflammatory and anti-psoriatic responses without the significant safety issues of other PDE4 inhibitors. Results of the two multiple ascending dose studies conducted by vTv to date will be presented at an upcoming scientific conference focused on dermatology.

With these results, vTv held a successful pre-IND meeting with the U.S. Food and Drug Administration Division of Dermatology and Dentistry. As a key outcome of the meeting, the Company obtained acknowledgement that the completed studies appear reasonable to support the proposed dosing regimen of 20mg/day for 12 weeks. In addition, the Company obtained feedback on the proposed safety monitoring and clinical trial endpoints. vTv plans to file an IND application later this year for a 12-week Phase 2 clinical trial evaluating the safety and efficacy of HPP737 in patients with moderate to severe psoriasis with study initiation targeted for early 2022.

"We are pleased that the study accomplished its objectives by confirming the anticipated favorable safety and tolerability profile of HPP737, particularly the absence of dose limiting gastrointestinal adverse events, at substantially higher concentrations than previously tested," said Steve Holcombe, chief executive officer, vTv Therapeutics. "An oral, once-daily PDE4 inhibitor with robust efficacy, absent adverse events of gastrointestinal distress, would be a significant benefit for patients with psoriasis. With FDA's feedback on our trial design we look forward to submitting the IND and beginning the Phase 2 trial in early 2022."

In addition to the Company's planned Phase 2 study in moderate to severe psoriasis, Newsoara Biopharma, the Company's strategic partner in Asia, is currently conducting Phase 2 studies in chronic obstructive pulmonary disease (COPD), psoriasis, and atopic dermatitis in China.

About HPP737
HPP737 is a novel, potent, orally administered PDE4 inhibitor discovered by vTv Therapeutics. HPP737 has been tested by vTv in three Phase 1 healthy volunteer clinical trials to date under an IND with the Division of Pulmonology, Allergy and Critical Care. HPP737 has been well tolerated across the range of doses tested, with few or no gastrointestinal adverse events, such as nausea, vomiting or diarrhea. vTv is filing a new IND for HPP737 with the Division of Dermatology and Dentistry to pursue HPP737 as a treatment for moderate-to-severe psoriasis.

About Psoriasis
Psoriasis is a chronic autoimmune inflammatory disease that impacts the skin and joints due to an imbalance of inflammatory cytokines. This results in the development of raised, red, silvery scale plaques on the skin (i.e. plaque psoriasis, psoriasis vulgaris) that has both medical implications and an impact on a patient's quality of life. While the specific trigger for this inflammatory imbalance is unknown, psoriasis may be caused by autoimmunity and genetic predisposition. Events such as trauma to the skin, stress, illness or infection that triggers the immune system, obesity, and weather have all been identified as contributing factors.

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, primary mitochondrial myopathy, and pancreatic cancer. 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

Source: vTv Therapeutics Inc.



Source: vTv Therapeutics Inc.