Vitae Pharmaceuticals Announces Positive Top-Line Results From a Phase 1 Multiple Ascending Dose Trial of VTP-43742

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- *Multiple ascending doses of VTP-43742 shown to be safe and generally well tolerated in healthy human volunteers*
- *Robust ex vivo biomarker response, suppressing secretion of pro-inflammatory IL-17A by more than 90 percent*
- *Top-line proof-of-concept clinical results from Phase 1 trial of VTP-43742 in psoriatic patients expected in the first quarter of 2016*

FORT WASHINGTON, Pa., Nov. 18, 2015 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company, today reported positive top-line results from the healthy human volunteer part of the multiple ascending dose Phase 1 clinical trial of VTP-43742. VTP-43742 is Vitae's wholly owned, orally active RORγt inhibitor with the potential to transform the treatment of multiple autoimmune disorders, including psoriasis, through the potent inhibition of IL-17 secretion from Th17 cells and blocking the action of IL-23.

In this double-blind, randomized, placebo-controlled trial examining the safety, tolerability, pharmacokinetic and pharmacodynamic profile of multiple oral doses of VTP-43742 in 40 healthy human volunteers, VTP-43742 was shown to be safe and generally well tolerated at all dose levels assessed. No serious adverse events were reported, and all study subjects completed the full 10 days of dosing. Vitae saw no drug-related clinical laboratory or electrocardiogram (ECG) abnormalities. Additionally, dose proportionality was demonstrated across all dose levels tested, and the half-life was consistent with once-a-day dosing.

In an *ex vivo* assay, VTP-43742 was also shown to suppress the RORγt dependent production of the pro-inflammatory cytokine IL-17A in blood obtained from study subjects. Those who received VTP-43742 showed a dose-dependent suppression of IL-17A production by more than 90 percent sustained for a full 24 hours in all but the lowest dose cohort. These results are consistent with the suppression of IL-17 production seen in Vitae's single ascending dose clinical trial of VTP-43742 in healthy human volunteers, for which results were disclosed in September 2015.

This clinical trial in healthy human volunteers is one part of Vitae's Phase 1 multiple ascending dose trial of VTP-43742. Top-line clinical efficacy results from the second part of the Phase 1 clinical trial, which is a proof-of-concept trial in patients with moderate to severe psoriasis, are expected in the first quarter of 2016.

"We continue to be very encouraged by the inhibition of IL-17 production that VTP-43742 has shown in our Phase 1 trials, along with its favorable safety and tolerability profile," said Dr. Richard Gregg, Chief Scientific Officer of Vitae. "These *ex vivo* results, combined with those seen in Vitae's previously disclosed single ascending dose trial, reaffirm our belief that VTP-43742's mechanism of action has the potential to safely and effectively treat psoriasis and an array of other autoimmune diseases. We look forward to obtaining top-line clinical proof-of-concept data from our trial in psoriasis patients in the first quarter of 2016."

Vitae's management team plans to discuss these top-line results from the healthy human volunteer part of the multiple ascending dose Phase 1 clinical trial of VTP-43742 and the development of the Company's other product candidates during an Analyst and Investor Briefing on Thursday, November 19, 2015 from 7:00 to 9:00 a.m. EST in New York, NY. Presentations will begin at 7:15 a.m. EST, and leading academic experts are scheduled to speak. For additional information and registration, please email vitae@westwicke.com or call 443-213-0506.

A live audio webcast of the event will be available via the "Investor Relations" page of the Vitae website, www.vitaepharma.com. Please log on through Vitae's website approximately 10 minutes before the scheduled start time. A replay of the webcast will be archived on Vitae's website for 90 days following the call.

About Psoriasis

Psoriasis, which affects approximately 7.5 million people in the U.S., is a chronic autoimmune disorder affecting the skin. It causes cells to rapidly multiply and build up on the skin's surface, resulting in red scaly patches that are often itchy and painful. Increased activity of a class of lymphocytes called Th17 cells, and the subsequent excess production of pro-inflammatory cytokines, including IL-17, by those cells are critical parts of the pathophysiology of psoriasis. RORγt is a nuclear hormone receptor that is essential for the formation and function of Th17 cells. Vitae believes that inhibiting RORγt activity in immune cells will be beneficial for the treatment of psoriasis, and potentially other autoimmune disorders.

About VTP-43742

VTP-43742 is Vitae's wholly owned, orally active RORγt inhibitor with the potential to transform the treatment of multiple autoimmune disorders, including psoriasis, through the potent inhibition of IL-17 secretion from Th17 cells and blocking the action of IL-23. In preclinical studies, VTP-43742 has been shown to inhibit RORγt activity, is highly selective versus other ROR isotypes, and has demonstrated potential for a human oral dosing schedule of once-a-day. The efficacy potential of VTP-43742 was demonstrated in an animal model of multiple sclerosis in direct comparison to an IL-17A monoclonal antibody. In September 2015, Vitae announced top-line results from a Phase 1 single ascending dose clinical trial in healthy human volunteers. Vitae also initiated an overlapping Phase 1 multiple ascending dose clinical trial in healthy human volunteers in August 2015, and in patients with moderate to severe psoriasis in September 2015.

About Vitae Pharmaceuticals

Vitae Pharmaceuticals is a clinical-stage biotechnology company developing first-in-class product candidates with potential to transform the treatment paradigm for patients with significant unmet medical needs. Initial indications being pursued include psoriasis, other autoimmune disorders, and atopic dermatitis. Vitae's lead clinical assets include VTP-43742, an oral RORγt inhibitor currently being studied in patients with moderate to severe psoriasis, and VTP-38543, an LXRβ selective agonist being studied for atopic dermatitis.

For additional information, please visit the company's website at www.vitaepharma.com.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the clinical development of VTP-43742. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan," "impending" or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward- looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Vitae is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in Vitae's forward-looking statements include, among others, the timing and success of preclinical studies and clinical trials conducted by Vitae and its collaborative partners; the ability to obtain and maintain regulatory approval of Vitae's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Vitae's product candidates; the size and growth of the potential markets for Vitae's product candidates and the ability to serve those markets; Vitae's expectations regarding Vitae's expenses and revenue, the sufficiency of Vitae's cash resources and needs for additional financing; Vitae's ability to attract or retain key personnel; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vitae's Annual Report on Form 10-K for the year ended December 31, 2014 and Vitae's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 which have been filed with the Securities and Exchange Commission (SEC). In addition to the risks described above and in Vitae's other filings with the SEC, other unknown or unpredictable factors also could affect Vitae's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Vitae

undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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