

Vitae Pharmaceuticals Initiates Second Part of a Phase 1 Multiple Ascending Dose Study of VTP-43742 in Psoriatic Patients

September 29, 2015 6:31 AM ET

Top-Line Proof-of-Concept Data in Psoriasis Patients Expected by the End of 2015

FORT WASHINGTON, Pa., Sept. 29, 2015 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company, today announced that it has initiated the second part of its Phase 1 multiple ascending dose clinical trial of VTP-43742 in psoriatic patients. VTP-43742 is the Company's wholly owned and first-in-class ROR γ t inhibitor product candidate for the treatment of autoimmune disorders, potentially including psoriasis, psoriatic arthritis, ankylosing spondylitis, rheumatoid arthritis and multiple sclerosis, as well as numerous orphan diseases.

In this proof-of-concept study, Vitae will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and clinical efficacy of multiple ascending doses of VTP-43742 in patients with moderate to severe psoriasis. The primary endpoint measure will be a percent change from baseline in the PASI (Psoriasis Area and Severity Index) score at four weeks. Top-line clinical efficacy results are expected by the end of 2015. This proof-of-concept part of the Phase 1 multiple ascending dose trial overlaps with the first part of the study currently being conducted in healthy human volunteers, which the Company initiated in August 2015.

"The initiation of this second part of our multiple ascending dose proof-of-concept trial marks Vitae's first assessment of the clinical efficacy of our novel and first-in-class ROR γ t inhibitor in a psoriatic patient population. This is a major step for the Company, and for determining whether VTP-43742 can provide a safe, effective and convenient oral treatment option for this patient population whose needs may not be satisfied by the current standards of care," said Dr. Richard Gregg, Chief Scientific Officer of Vitae.

About Autoimmune Disorders

Autoimmune disorders, where a patient's own immune system attacks normal tissue, make up a large number of human disorders. 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 many human autoimmune disorders. ROR γ t is a nuclear hormone receptor that is essential for the formation and function of Th17 cells. Vitae believes inhibition of excess ROR γ t activity in immune cells will be beneficial for the treatment of multiple autoimmune disorders, potentially including psoriasis, psoriatic arthritis, ankylosing spondylitis, rheumatoid arthritis and multiple sclerosis, as well as numerous orphan diseases.

About VTP-43742

VTP-43742 is Vitae's wholly owned product candidate for the treatment of a variety of autoimmune disorders. In preclinical studies, VTP-43742 inhibits the activity of ROR γ t and has demonstrated potent inhibition of IL-17 secretion from Th17 cells. It is highly selective versus other ROR isotypes, and has demonstrated 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. Vitae previously disclosed results from a Phase 1 single ascending dose clinical trial in healthy human volunteers in September 2015. The Company also initiated an overlapping Phase 1 multiple ascending dose clinical trial in healthy human volunteers in August 2015.

About Vitae Pharmaceuticals

Vitae Pharmaceuticals is a clinical-stage biotechnology company focused on discovering and developing first-in-class, small molecule drugs for difficult-to-drug disease targets that can potentially address significant unmet medical needs, including programs in autoimmune disorders, atopic dermatitis, Alzheimer's disease and diabetes. This robust and growing portfolio

of novel product candidates is generated internally by Contour®, Vitae's proprietary structure-based drug discovery platform.

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 June 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.

CONTACT: INVESTORS:

Vitae Pharmaceuticals, Inc.
Richard S. Morris, CPA
Chief Financial Officer
(215) 461-2000
rmorris@vitaerx.com

Westwicke Partners
John Woolford
(443) 213-0506
john.woolford@westwicke.com

MEDIA:

6 Degrees PR
Tony Plohoros
(908) 591-2839
tplohoros@6degreespr.com

 [Vitae Logo](#)

Vitae Pharmaceuticals