Vitae Pharmaceuticals Announces Initiation of a Phase 1 Single Ascending Dose Study of VTP-43742 in Autoimmune Disorders

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FORT WASHINGTON, Pa., June 29, 2015 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company, today announced the initiation of a Phase 1 single ascending dose clinical trial of VTP-43742, the Company's wholly owned and potential first-in-class RORγt inhibitor for the treatment of autoimmune disorders, including psoriasis, multiple sclerosis, and various arthropathies, as well as rare and orphan disorders.

This single ascending dose trial will assess the safety, tolerability, pharmacokinetics and pharmacodynamics of VTP-43742 in healthy human volunteers, with results expected in the second half of 2015. The Company also intends to initiate an overlapping Phase 1 multiple ascending dose, proof-of-concept clinical trial of VTP-43742 in the third quarter, which will include patients with moderate to severe psoriasis. Top-line clinical efficacy results from this second clinical trial are expected by the end of the year.

"The initiation of this Phase 1 study of our wholly owned first-in-class RORγt inhibitor is a very important milestone both for Vitae and for patients afflicted with autoimmune disorders," said Dr. Richard Gregg, Chief Scientific Officer of Vitae. "We believe that VTP-43742's unique mechanism of action has the potential to provide patients with a safe, effective and convenient oral treatment option for a variety of autoimmune disorders."

About Autoimmune Disorders

Autoimmune disorders, where the immune system attacks normal tissue, make up a large number of human disorders including psoriasis, multiple sclerosis, rheumatoid arthritis and steroid-resistant asthma, as well as rare or orphan disorders. Increased activity of a class of lymphocytes called Th17 cells and excess production of pro-inflammatory proteins, including Interleukin 17, or IL-17, by these cells are critical parts of the pathophysiology of many human autoimmune disorders. RORγt is a nuclear hormone receptor that is essential for the formation and function of Th17 cells. Vitae Pharmaceuticals believes inhibition of RORγt activity in Th17 cells will be beneficial for the treatment of multiple autoimmune disorders.

About VTP-43742

VTP-43742 is Vitae Pharmaceuticals' wholly owned product candidate for the treatment of a variety of autoimmune disorders. In preclinical studies, VTP-43742 demonstrated potent inhibition of IL-17 secretion from Th17 cells, was highly selective versus other ROR isotypes, and has a predicted human oral dosing schedule of once-a-day. VTP-43742 also demonstrated superiority in an animal model of multiple sclerosis in direct comparison to an IL-17A monoclonal antibody. Vitae has filed an Investigational New Drug Application with the U.S. Food and Drug Administration for VTP-43742 and initiated a Phase 1 single ascending dose clinical trial in healthy human volunteers to assess safety, tolerability, pharmacokinetics and pharmacodynamics.

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 disclosed programs in diabetes, Alzheimer's disease, autoimmune disorders, atopic dermatitis and acute coronary syndrome. 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 March 31, 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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