

Vitae Pharmaceuticals Opens Phase 2a Proof-of-Concept Trial of VTP-38543 in Atopic Dermatitis Patients

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FORT WASHINGTON, Pa., Dec. 10, 2015 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company, today announced updated plans to begin clinical development of VTP-38543 with a four-week Phase 2a proof-of-concept trial that has been opened for patients with atopic dermatitis (AD). Previously, the Company had expected to initiate a Phase 1 clinical trial. The Company has started activities to initiate the Phase 2a trial and expects to begin dosing patients within the next month. VTP-38543 is the Company's topical LXR β selective agonist for the treatment of AD, a skin condition characterized by an intense itch / scratch cycle and driven by both inflammation and a breakdown of the skin's barrier function.

This proof-of-concept trial will be Vitae's first assessment of VTP-38543 in humans, and is a randomized, double-blind trial to evaluate the safety, tolerability, efficacy, pharmacokinetics and pharmacodynamics of multiple ascending topical doses of VTP-38543 in approximately 100 adult patients with mild to moderate AD. Top-line results from this trial are expected in the second half of 2016.

"Atopic dermatitis represents a significant unmet medical need, with a health-related quality of life impact exceeding that of asthma, epilepsy and diabetes. Current therapies address the inflammation associated with the disease, but do not directly address the accompanying breakdown of the skin's barrier function, which can be an important independent driver of the disease process," said Dr. Richard Gregg, Chief Scientific Officer of Vitae. "We are eager to begin this Phase 2a study to get an early read on VTP-38543's ability to address both aspects of atopic dermatitis and potentially deliver benefit to those suffering from this condition."

About Atopic Dermatitis

Atopic dermatitis (AD) is a skin condition affecting approximately 17.5 million infants, adolescents and adults in the U.S. It is characterized by intense itching and is caused by both inflammation and a breakdown of the skin's barrier function. Activation of LXR in skin keratinocytes, the most common cell type in the outer layer of skin, has been shown to increase the formation of corneocytes and the production of lamellar lipids (the 'bricks and mortar' of the outer layer of skin). LXR activation also has been shown to have an anti-inflammatory effect in skin equivalent to a high potency corticosteroid. Vitae believes that increasing LXR activity with VTP-38543 may be beneficial for AD patients by both decreasing skin inflammation and repairing the damaged outer layer of skin.

About VTP-38543

VTP-38543 is Vitae's LXR β selective agonist with the potential to significantly impact the treatment of atopic dermatitis (AD), a common inflammatory skin disease. In preclinical studies, VTP-38543 was shown to increase LXR activity, decrease skin inflammation, and increase the production and secretion of lipids necessary for maintaining the barrier function, resulting in a potentially superior therapy for AD.

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 ROR γ t inhibitor currently being studied in patients with moderate to severe psoriasis, and VTP-38543, an LXR β 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-38543. 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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