Vitae Pharmaceuticals Achieves Proof-of-Concept with First-in-Class RORγt Inhibitor in Moderate to Severe Psoriasis

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VTP-43742 demonstrated statistically significant efficacy and was well tolerated

Company plans to move VTP-43742 forward into 16-week study

Conference call to discuss results at 5:00 p.m. ET, March 16, 2016

James Krueger, M.D., Ph.D., Head of the Laboratory for Investigative Dermatology at Rockefeller University, to join call

FORT WASHINGTON, Pa., March 16, 2016 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company, today announced positive top-line results from its Phase 2a proof-of-concept clinical trial of VTP-43742 in psoriatic patients. VTP-43742 is Vitae's wholly owned, first-in-class, 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.

This randomized, double-blind, placebo-controlled trial assessed the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of multiple oral doses of VTP-43742 in patients with moderate to severe psoriasis over a four-week period. VTP-43742 demonstrated a clear signal of efficacy, with patients in the 350 mg dose group achieving a 24 percent reduction in the Psoriasis Area Severity Index (PASI) score relative to placebo. In the 700 mg dose group, patients achieved a 30 percent placebo-adjusted PASI score reduction. For both doses, we observed clinically relevant and statistically significant reductions ($p<0.015$) relative to baseline values.

Between weeks zero and two, there was a modest onset of PASI reduction, and for the last weeks of the study, and particularly between weeks three and four, there was an acceleration of the rate of reduction in PASI score in both the 350 mg and 700 mg dose groups, suggesting the potential for greater reductions in PASI scores with longer duration of treatment. While full efficacy in psoriasis is not generally seen until at least 12 weeks of continuous therapy, the PASI score reductions observed for VTP-43742 at four weeks, and the acceleration of rate of PASI reduction between weeks three and four, are consistent with the potential to achieve greater oral efficacy in the treatment of psoriasis. VTP-43742 was shown to be generally well tolerated at all dose levels tested, with no serious adverse events reported. No drug-related electrocardiogram (ECG) abnormalities were observed. In the 700 mg dose group, reversible transaminase elevations were observed in four patients. Pharmacokinetics were consistent with once-a-day dosing.

“We believe these data validate RORγt as an exciting and novel therapeutic target for the treatment of psoriasis and other autoimmune disorders,” said Jeff Hatfield, President and Chief Executive Officer of Vitae. “While the autoimmune market is currently dominated by injectable antibody therapy, we believe VTP-43742 has the potential to expand utilization of oral therapy in a variety of autoimmune disorders, such as psoriasis, psoriatic arthritis, rheumatoid arthritis, multiple sclerosis and inflammatory bowel disease with an effective, safe and well tolerated, once-a-day agent.”

In biomarker assays measuring plasma IL-17A and IL-17F, the 350 mg and 700 mg doses of VTP-43742 were shown to decrease both plasma cytokines by up to 75 percent, and these decreases were statistically significant ($p<0.02$), consistent with the change in PASI score from baseline.

“We plan to advance VTP-43742 into a larger scale 16 week trial in the second half of 2016 to continue to assess the efficacy, safety and tolerability of our first-in-class drug candidate,” said Dr. Richard Gregg, Chief Scientific Officer of Vitae. “We look forward to presenting the complete results of this Phase 2a trial at future medical meetings.”

Conference Call

Vitae's management team will host a conference call and webcast today, March 16, 2016 at 5:00 p.m. ET to discuss these top-line proof-of-concept results and next steps for VTP-43742. Presentation slides will be available via the webcast link. A question and answer session with the Vitae management team and James Krueger, M.D., Ph.D., Head of the Laboratory for Investigative Dermatology at Rockefeller University, will follow Vitae's remarks. To participate on the live call, please dial 844-423-9893 (domestic) or +1-716-247-5808 (international), and provide the conference ID 73110204, approximately five to 10 minutes ahead of the start of the call.

A live audio webcast of the call 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 prior to 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-17A and IL-17F, 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 observed to inhibit RORγt activity, is highly selective versus other ROR isotypes, and has a human oral dosing schedule of once-a-day. The efficacy potential of VTP-43742 was demonstrated in an animal model of multiple sclerosis where it was observed to be superior in direct comparison to an IL-17A monoclonal antibody. In September 2015 and November 2015, Vitae announced top-line results from a Phase 1 single ascending dose clinical trial and a Phase 1 multiple ascending dose trail, respectively, in healthy human volunteers. In March 2016, Vitae announced top-line results from a Phase 2a randomized, double-blind, placebo-controlled clinical trial in patients with moderate to severe psoriasis.

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 RORgt inhibitor currently being studied in patients with moderate to severe psoriasis, and VTP-38543, an LXRβ selective agonist being studied in patients with mild to moderate 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 but not limited to statements related to pharmaceutical development of VTP-43742 and future prospects. These forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from our expectations. These risks include, but are not limited to those 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, 2015, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov.

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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