Vitae Pharmaceuticals Reports Top-Line Results From Remaining Monotherapy Arm of Phase 2 Clinical Trial of BI187004 in Overweight Type 2 Diabetes Patients

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FORT WASHINGTON, Pa., Dec. 17, 2015 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company, today announced top-line clinical efficacy results from the remaining monotherapy arm of Boehringer Ingelheim's Phase 2 proof-of-concept trial of BI187004 (VTP-34072) in type 2 diabetes.

This randomized, double-blind, placebo-controlled Phase 2 proof-of-concept trial assessed the safety, tolerability, efficacy, pharmacokinetics and pharmacodynamics of BI187004 as monotherapy and as an add-on to metformin background therapy over a period of 28 days in patients with type 2 diabetes mellitus. In June 2015, Vitae reported that top-line results from the metformin arm of the Phase 2 trial did not meet the predefined primary efficacy endpoint criteria (fasting glucose lowering). As Vitae anticipated based on these earlier results, in this remaining monotherapy arm of the trial, BI187004 did not achieve the predefined primary efficacy endpoint criteria. As a result, Boehringer Ingelheim has informed Vitae of its intention to terminate the program and its corresponding license agreement. Vitae has no current plans to continue the program independently, but will assess options during the coming months.

About BI187004 / VTP-34072

BI187004, an 11β HSD1 inhibitor, was discovered using Vitae's proprietary Contour® platform, and was being developed by Boehringer Ingelheim for the treatment of type 2 diabetes and metabolic syndrome in the framework of a partnership. In preclinical studies, BI187004 had a positive impact on multiple cardiovascular and metabolic risk factors associated with metabolic syndrome, which differentiates it from other classes of type 2 diabetes drugs.

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 to be 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 statements regarding the status of the 11β research collaboration and license agreement and the clinical development of BI-187004. 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.

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 Pharmaceuticals, Inc.