Vitae Pharmaceuticals Announces Top-Line Results From Metformin Arm of Ongoing Phase 2 Clinical Trial of BI187004/VTP-34072 in Overweight Type 2 Diabetics

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FORT WASHINGTON, Pa., June 29, 2015 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company, today announced top-line clinical efficacy results from the metformin arm of an ongoing Phase 2 proof-of-concept clinical trial of BI187004/VTP-34072 in the treatment of overweight type 2 diabetic patients. BI187004/VTP-34072 is a potential first-in-class 11β-hydroxysteroid dehydrogenase type 1 (11β HSD1) inhibitor that was discovered by Vitae and is currently being developed by Boehringer Ingelheim GmbH (Boehringer Ingelheim), a leader in diabetes treatments and cardiometabolic research and development.

Safety, tolerability, efficacy, pharmacokinetics and pharmacodynamics of BI187004/VTP-34072 as monotherapy or as an add-on to metformin background therapy are being investigated over 28 days in a randomized, double-blind, placebo-controlled study in patients with type 2 diabetes mellitus. Primary efficacy data (fasting plasma glucose) from the metformin arm did not meet Boehringer Ingelheim's predefined endpoint criteria. Data from the placebo-controlled monotherapy arm of the trial, which is still ongoing, are expected to be reported later this year. Together, these data sets will be used by Boehringer Ingelheim to determine appropriate next steps for BI187004/VTP-34072.

"The metabolically complex, overweight type 2 diabetic patient population is in need of novel mechanisms of action that can address their overall risk profile," said Dr. Richard Gregg, Chief Scientific Officer of Vitae. "We are anxious to learn more about BI187004/VTP-34072 when the study is completed and fully analyzed."

About Type 2 Diabetes

Type 2 diabetes is a common and increasingly prevalent disease. According to the American Diabetes Association, in 2015, approximately 20 million Americans had a diagnosis of type 2 diabetes and another 7.7 million were undiagnosed and unaware that they had type 2 diabetes. If the present trends continue, as many as one in three American adults are expected to have type 2 diabetes by 2050. Overall, the economic cost of diagnosed type 2 diabetes in the United States was estimated to be $245 billion in 2012 and, of that, approximately $9.6 billion was spent on type 2 diabetes drugs. Patients with metabolic syndrome, which affects approximately 85 percent of patients with type 2 diabetes, are characterized by being overweight and having elevated glucose, blood pressure, cholesterol and triglycerides, while having decreased levels of HDL-C or "good cholesterol."

About BI187004/VTP-34072

BI187004/VTP-34072 is an 11β HSD1 inhibitor that was discovered using Vitae's proprietary Contour® platform and is being developed by Boehringer Ingelheim. BI187004/VTP-34072 is being studied for the treatment of type 2 diabetes and metabolic syndrome, and is Vitae's most advanced product candidate. In preclinical studies, BI187004/VTP-34072 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. BI187004/VTP-34072 is currently being studied in an ongoing Phase 2 proof-of-concept trial assessing efficacy and tolerability in diabetic patients on stable doses of metformin and as monotherapy.

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-34072. 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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