

## **Vitae Reports Positive Clinical Data in Chronic Kidney Disease Program at the American Diabetes Association's 71st Scientific Sessions**

**- Phase I Findings for VTP-27999 Show Potential for Superior Renal Protection -**

**- Phase 2b Study Planned for First Quarter 2012 -**

**Fort Washington, PA, June 27, 2011** -- Vitae Pharmaceuticals today announced results of a Phase I clinical study in healthy volunteers demonstrating the Company's lead compound, VTP-27999, significantly reduced the activity of the renin-angiotensin-aldosterone system (RAAS) in the kidney. The RAAS pathway is considered to have a central role in the progression of chronic kidney disease, particularly in diabetes, and diabetic nephropathy is the leading cause of end-stage renal disease (ESRD). The clinical findings were presented in a poster presentation titled, "VTP-27999: A Novel Direct Renin Inhibitor with Potential for Superior Renal Protection in Diabetic Nephropathy", at the 71st Scientific Sessions of the American Diabetes Association being held in San Diego, California, from June 24 to 28.

In Vitae's Phase I study, administration of VTP-27999 resulted in greater than 90% inhibition of plasma renin activity (PRA) at all doses tested. In addition, large dose-dependent compensatory increases in a key biomarker of RAAS pathway inhibition in the kidney were seen. The highest dose of VTP-27999 increased the biomarker nearly four times as much as the highest marketed dose of aliskiren, the active comparator.

Dr. Matt Weir, Professor of Medicine at the University of Maryland, commented, "Diabetic nephropathy is a complication of diabetes that typically has an inexorable progression, even with the use of current therapies, such as ACE inhibitors or ARBs. Direct renin inhibition in the kidney, the site of renin production, holds great promise to provide improved renal protection. I look forward to further news from Vitae's program."

A novel, potent and selective renin inhibitor, VTP-27999 is designed to offer a best-in-class therapeutic profile – most importantly, improved nephroprotection. VTP-27999 demonstrated significant nephroprotective effects in preclinical *in vivo* studies, including a clear survival benefit.

"We are very pleased with the results of the Phase I study. We achieved important biomarker data confirming the potential for superior renoprotective effects with VTP-27999 and showing a consistent dose relationship across all doses administered. In addition, this study continued to demonstrate that the compound is well-tolerated – we saw no significant adverse events and no drug-related discontinuations from therapy," stated Vitae's Chief Scientific Officer, Richard E. Gregg, M.D. "In addition, pharmacokinetic data showed a once-daily dosing profile and oral bioavailability approximating 30%. These findings are in line with the preclinical research, and we anticipate publishing the clinical results in a peer reviewed journal within the next year."

Vitae President and Chief Executive Officer Jeffrey Hatfield said, "Chronic kidney disease is a significant and growing health issue strongly linked to the world's rapidly rising incidence of diabetes. Based on the positive results of the full VTP-27999 Phase 1 program, we are completing the design of the Phase 2b protocol which could initiate by the beginning of 2012, with results available as early as the end of 2012.

We are excited to be rapidly advancing VTP-27999, with the hope that it will someday make a real difference in the lives of patients suffering from chronic kidney disease.”

### **About the RAAS Pathway and Chronic Kidney Disease**

Renin is the first and rate-limiting step in the RAAS pathway, the primary pathway for regulating renal hemodynamics. Over-activation of the RAAS system is directly linked to the pathophysiology of chronic kidney disease. Drugs that directly inhibit renin and more effectively block the RAAS pathway are expected to offer improved kidney protection and improved patient outcomes.

The prevalence of chronic kidney disease (CKD) has risen more than 25% over the last decade. Current treatments for diabetic CKD focus on controlling diet and glucose levels with oral drugs and insulin, and blood pressure through anti-hypertensive drugs. While these approaches can slow the development of CKD, patients still progress to end-stage renal disease (ESRD), which is life-threatening and requires aggressive, invasive therapy including hemodialysis and renal transplantation. VTP-27999 has been developed specifically for its direct effects in the kidney to alter the course of CKD.

### **About Vitae Pharmaceuticals**

Vitae Pharmaceuticals is a clinical-stage biopharmaceutical company discovering and developing a portfolio of novel, small molecule, best-in-class compounds that important disease areas, including: chronic kidney disease, diabetes, Alzheimer’s disease and atherosclerosis. Vitae’s lead compound, VTP-27999, is a wholly owned, novel, potent and selective renin inhibitor offering the potential for superior renal protection in patients suffering from chronic kidney disease. The compound has completed Phase I clinical studies and is expected to enter Phase 2b in early 2012.

Vitae is expert in structure-based drug discovery and combines a proprietary technical platform with the experience and insight of world class scientists to advance best-in-class compounds for high value, hard-to-drug targets. Vitae’s proprietary, discovery platform has clear advantages in creating and analyzing novel drug candidates that meet pre-defined physicochemical and biochemical characteristics. The accuracy and speed of this system has enabled Vitae to solve challenging targets in multiple therapeutic areas – discovering and advancing attractive compounds in a rapid and highly capital efficient manner. Vitae Pharmaceuticals is financed by leading corporate and venture capital investors; its last venture round was in 2004. Vitae’s 45 scientists are located in Fort Washington, Pennsylvania. For additional information, please visit the company’s website, [www.vitaepharma.com](http://www.vitaepharma.com).

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