Gilead Initiates Phase II Clinical Trial of Cicletanine for the Treatment of Pulmonary Arterial Hypertension

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Mar. 24, 2009-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that it has begun enrolling patients in a Phase II clinical trial of cicletanine hydrochloride (cicletanine), an oral agent in development for the treatment of pulmonary arterial hypertension (PAH). The study is designed to compare the efficacy, safety and tolerability of cicletanine to placebo in patients with PAH and will enroll 160 patients at approximately 60 investigational sites worldwide.

“Preclinical and early clinical data suggest that cicletanine may offer an alternative oral treatment for PAH, potentially working through a mechanism of action that differs from existing therapies for this disease,” said Seigo Izumo, MD, Gilead’s Senior Vice President, Cardiovascular Therapeutics. “We are pleased to be moving cicletanine into the next phase of clinical development, as we continue to build a pipeline of therapies for PAH and other serious cardiovascular diseases that represent significant unmet medical need.”

About the Cicletanine Phase II Study

The cicletanine Phase II study is a randomized, double-blind, placebo-controlled, multicenter, dose-ranging study designed to evaluate the safety, efficacy and tolerability of cicletanine for treatment of PAH (WHO Group 1). The primary efficacy endpoint is the change from baseline in six-minute walk distance (6MWD) after 12 weeks of treatment. Secondary endpoints include time to clinical worsening of PAH during the 12-week placebo-controlled treatment period and change from baseline after 12 weeks in Borg dyspnea index (BDI, a measure of breathing ability), WHO functional class, SF-36® Health Survey physical functioning scale and various hemodynamic measures. Eligible patients include those not currently receiving treatment for PAH as well as those who are currently being treated with an approved endothelin receptor antagonist (ERA).

A total of 160 patients (40 per treatment arm) will be randomized (1:1:1:1) to receive either placebo, 150 mg cicletanine administered once daily, 150 mg cicletanine administered twice daily or 300 mg administered once daily. Patients who complete the 12-week placebo-controlled period will be eligible for long-term treatment with cicletanine.

Additional information about the study can be found at www.clinicaltrials.gov.

About Cicletanine

Cicletanine is an oral agent invented and developed by Ipsen (Euronext: IPN), an international specialty pharmaceutical group. Cicletanine is approved in certain European countries as a once-daily monotherapy treatment for hypertension. Endothelial dysfunction, known to play a role in hypertension and PAH, is associated with a deficiency in vascular nitric oxide. Current data suggest that cicletanine may enhance vascular nitric oxide availability and vasorelaxation. While the relationship between endogenous vascular nitric oxide concentrations and PAH pathology remains unclear, the positive effects of providing supplemental nitric oxide to PAH patients have been demonstrated, indicating that enhancement of endogenous nitric oxide concentrations with cicletanine may prove beneficial.

In July 2005, Ipsen licensed to Navitas Assets LLC, patents and know-how to develop and distribute (i) cicletanine combination therapy worldwide and (ii) cicletanine monotherapy in the United States. Ipsen retains monotherapy rights outside the U.S. In May 2008, Gilead acquired all of the Navitas assets related to cicletanine.

Cicletanine has been granted orphan drug status for treatment of PAH by the U.S. Food and Drug Administration (FDA). Cicletanine is an investigational therapy and has not yet been determined safe or efficacious in humans.

About Pulmonary Arterial Hypertension

PAH is a debilitating disease characterized by constriction of the blood vessels in the lungs leading to high pulmonary arterial pressures. These high pressures make it difficult for the heart to pump blood through the lungs to be oxygenated. Patients with PAH suffer from shortness of breath as the heart struggles to pump against these high pressures, causing such patients to ultimately die of heart failure. PAH can occur with no known underlying cause, or it can occur secondary to diseases such as connective tissue disease, congenital heart defects, cirrhosis of the liver and HIV infection. PAH afflicts approximately 200,000 patients worldwide.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Australia.

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors, including the risks related to our ability to enroll patients in the Phase II clinical trial as planned, the possibility of unfavorable results of the clinical trial, the need to modify or delay our clinical trial or to perform additional trials and the risk of failing to obtain FDA and other regulatory body approvals. As a result, cicletanine for PAH may never be successfully commercialized. Further, we may make a strategic decision to discontinue development of cicletanine for PAH if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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Gilead Sciences, Inc.
Susan Hubbard, 650-522-5715 (Investors)
Nathan Kaiser, 650-522-1853 (Media)