Gilead Initiates Letairis(R) (ambrisentan) Phase IV Program

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-- First Phase IV Study (ATHENA-1) Will Evaluate Letairis in Pulmonary Arterial Hypertension Patients Demonstrating a Sub-Optimal Response to Sildenafil Monotherapy --

FOSTER CITY, Calif.--(BUSINESS WIRE)--May 1, 2008--Gilead Sciences, Inc. (Nasdaq:GILD) today announced the initiation of ATHENA-1, a Phase IV, randomized, double-blind, placebo-controlled study evaluating Letairis(R) (ambrisentan 5 mg and 10 mg tablets) in patients with pulmonary arterial hypertension (PAH) demonstrating a sub-optimal response to sildenafil monotherapy. ATHENA-1 is the first of several Phase IV Letairis studies Gilead plans to initiate in 2008 and 2009. Letairis is currently approved as a once-daily treatment for PAH (WHO Group 1) in patients with WHO functional class II or III symptoms to improve exercise capacity and delay clinical worsening.

"The PAH research community has made great progress over the last several decades in developing therapies for patients, including establishing an understanding of the role of therapies targeting different disease pathways," said Norbert Bischofberger, Executive Vice President of Research and Development and Chief Scientific Officer at Gilead. "With our Phase IV program, we hope to contribute to the growing body of knowledge about this disease."

About ATHENA-1

ATHENA-1 will evaluate whether the addition of Letairis to sildenafil is safe and effective in PAH patients who have not demonstrated an optimal response on sildenafil therapy alone. The primary objective of this study is to compare the change in pulmonary vascular resistance (PVR), or the resistance to blood flow caused by constricted lung blood vessels. A progressive increase in PVR is a measurable biological characteristic of PAH.

A total of 80 patients (40 in each arm) will be randomized to receive either Letairis or placebo, in addition to sildenafil at their current dose. The primary endpoint is the change from baseline in PVR after 24 weeks of treatment. Long-term safety and efficacy measures will be examined for up to one year (48 weeks).

Additional information regarding ATHENA-1 can be found at www.clinicaltrials.gov.

Letairis is not indicated for use in combination with sildenafil for treatment of PAH.

Full prescribing information for Letairis is available at www.gilead.com and at http://www.letairis.com/downloads/LETAIRIS_prescribing_information.pdf .

WARNING: POTENTIAL LIVER INJURY

Letairis can cause elevation of liver aminotransferases (ALT and AST) to at least three times the upper limit of normal (ULN). Letairis treatment was associated with aminotransferase elevations greater than three times ULN in 0.8 percent of patients in 12-week trials and 2.8 percent of patients including long-term open-label trials out to one year. One case of aminotransferase elevations greater than three times ULN has been accompanied by bilirubin elevations greater than two times ULN. Because these changes are a marker for potentially serious liver injury, serum aminotransferase levels (and bilirubin if aminotransferase levels are elevated) must be measured prior to initiation of treatment and then monthly.

Elevations in aminotransferases require close attention. Letairis should generally be avoided in patients with elevated aminotransferases greater than three times ULN at baseline because monitoring liver injury may be more difficult. If liver aminotransferase elevations are accompanied by clinical symptoms of liver injury (such as nausea, vomiting, fever, abdominal pain, jaundice, or unusual lethargy or fatigue) or increases in bilirubin greater than two times ULN, treatment should be stopped. There is no experience with the re-introduction of Letairis in these circumstances.

CONTRAINDICATION: PREGNANCY

Letairis is very likely to produce serious birth defects if used by pregnant women, as this effect has been seen consistently when it is administered to animals. Pregnancy must therefore be excluded before the initiation of treatment with Letairis and prevented thereafter by the use of at least two reliable methods of contraception unless the patient is unable to become pregnant. Obtain monthly pregnancy tests.

About the Letairis Education and Access Program (LEAP)

Because of the risks of liver injury and birth defects, Letairis is available only through a special restricted distribution program called the Letairis Education and Access Program (LEAP) by calling 1-866-664-LEAP (1-866-664-5327). Only prescribers and pharmacies registered with LEAP are able to prescribe and distribute Letairis. In addition, Letairis may be dispensed only to patients who are enrolled in and meet all conditions of LEAP.

Important Safety Information

Elevations of liver aminotransferases have been reported with Letairis and serious liver injury has been reported with related drugs. Patients should be monitored monthly for liver aminotransferases and treatment with Letairis should be discontinued if greater than five times the upper limit of normal or if signs or symptoms of liver dysfunction are observed.

For women of childbearing potential, Letairis treatment should only be initiated after a negative pregnancy test and only in those using at least two reliable methods of contraception.

Decreases in hemoglobin concentration and hematocrit have followed administration of other endothelin receptor antagonists and were observed in clinical studies with Letairis. These decreases were observed within the first few weeks of treatment with Letairis, and stabilized thereafter.

Peripheral edema is a known class effect of endothelin receptor antagonists and is also a clinical consequence of PAH and worsening PAH. In the placebo-controlled studies, there was an increased incidence of peripheral edema in patients treated with doses of 5 or 10 mg of Letairis compared to placebo. Most edema was mild to moderate in severity. Peripheral edema was similar in younger patients (age less than 65 years) receiving Letairis (14 percent; 29/205) or placebo (13 percent; 13/104), and was greater in elderly patients (age greater than or equal to 65 years) receiving Letairis (29 percent; 16/56) compared to placebo (4 percent, 1/28). The results of such subgroup analyses must be interpreted cautiously.

In addition, there have been post-marketing reports of fluid retention in patients with pulmonary hypertension, occurring within weeks after starting Letairis. Patients required intervention with a diuretic, fluid management, or, in some cases, hospitalization for decompensating heart failure. Because the post-marketing experience was reported voluntarily from a population of uncertain size, it is not possible to reliably estimate the relative frequency or establish a causal relationship to Letairis drug exposure.

Caution should be used when Letairis is co-administered with cyclosporine A, as it may cause increased exposure to Letairis.

Caution should be used when Letairis is co-administered with strong CYP3A-inhibitors (e.g., ketoconazole) or CYP2C19-inhibitors (e.g., omeprazole).

The most common adverse events that occurred at a higher frequency among Letairis-treated patients compared to placebo included (placebo-adjusted frequency): peripheral edema (6 percent), nasal congestion (4 percent), sinusitis (3 percent), flushing (3 percent), palpitations (3 percent), nasal pharyngitis (2 percent), abdominal pain (2 percent), constipation (2 percent), dyspnea (1 percent) and headache (1 percent).

No clinically relevant interactions of Letairis with warfarin or sildenafil have been observed.

Letairis is not recommended in patients with moderate to severe hepatic impairment.

About Letairis

Letairis (ambrisentan) is an endothelin receptor antagonist that has a high affinity for the endothelin type-A (ETA) receptor. Activation of the ETA receptor by endothelin-1 (ET-1), a small peptide hormone, leads to vasoconstriction (narrowing of blood vessels) and cell proliferation. The clinical impact of high selectivity for ETA is not known. Endothelin concentrations are higher in the lung tissue of PAH patients, thus suggesting that ET-1 may play a critical role in the pathogenesis or progression of PAH.

GlaxoSmithKline (GSK) holds rights to commercialize ambrisentan for PAH in territories outside of the United States. On April 25, 2008, GSK announced that the European Commission issued a marketing authorisation for ambrisentan, under the tradename Volibris(R), for the treatment of PAH in patients classified as WHO functional class II and III, to improve exercise capacity. GSK has stated that its first European launches of Volibris are planned in the summer of 2008.

About Pulmonary Arterial Hypertension (WHO Group 1)

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 risks related to Gilead's ability to initiate additional Phase IV Letairis studies in 2008 and 2009. 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, 2007, 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.

Letairis is a registered trademark of Gilead Sciences, Inc.

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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