U.S. Food and Drug Administration Approves Gilead's Letairis(TM) (ambrisentan) 5 mg and 10 mg Tablets for the Once-Daily Treatment of Pulmonary Arterial Hypertension (WHO Group 1) in Patients with WHO Functional Class II or III Symptoms

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Gilead Also Announces Launch of Gilead(TM)Solutions, a Comprehensive Access Program

FOSTER CITY, Calif.--(BUSINESS WIRE)--June 15, 2007--Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the U.S. Food and Drug Administration (FDA) has granted approval of Letairis(TM) (ambrisentan) 5 mg and 10 mg tablets. Letairis is an endothelin receptor antagonist (ERA) indicated for the once-daily treatment of pulmonary arterial hypertension (WHO Group 1) in patients with WHO Functional Class II or III symptoms to improve exercise capacity and delay clinical worsening. Letairis will be available in the United States early next week. Because of the risks of liver injury and birth defects, the product will be available through the Letairis Education and Access Program (LEAP), a restricted distribution program designed to help patients learn about the risks of Letairis.

"PAH is a debilitating and life-threatening disease for which there remains a significant need for new treatments," said Lewis J. Rubin, MD, Professor of Medicine, University of California, San Diego. "The availability of new treatments such as ambrisentan is critical to our ability to help patients living with this serious disease."

"All of us at Gilead extend our thanks to the investigators and patients who took part in the Letairis clinical trials, and we appreciate the hard work of the U.S. FDA to ensure this product reaches those in need as quickly as possible," said John C. Martin, PhD, President and CEO of Gilead Sciences. "As a company dedicated to advancing therapeutics for diseases that represent significant unmet medical needs, we look forward to partnering with the PAH community to help patients living with this disease."

In two randomized, double-blind, 12-week, placebo-controlled Phase III clinical trials (ARIES-1 and ARIES-2) involving a total of 393 patients, treatment with Letairis resulted in a significant improvement in six-minute walk distance. An increase in walk distance was observed after four weeks of treatment with each dose regimen of Letairis, with a dose-response observed after 12 weeks of treatment. In ARIES-1, placebo-adjusted mean and median changes from baseline of 31 meters and 27 meters (p=0.008), respectively, were observed for the 5 mg dose. Placebo-adjusted mean and median changes from baseline of 51 meters and 39 meters (p less than 0.001), respectively, were observed for the 10 mg dose. In ARIES-2, placebo-adjusted mean and median changes from baseline of 59 meters and 45 meters (p less than 0.001), respectively, were observed for the 5 mg dose.

Treatment with Letairis also significantly delayed time to clinical worsening of PAH. Clinical worsening was defined as the first occurrence of death, lung transplantation, hospitalization for PAH, atrial septostomy, study withdrawal due to the addition of other PAH therapeutic agents, or study withdrawal due to early escape (progressive disease).

The long-term follow-up of the patients who were treated with Letairis in the two pivotal studies and the open-label extension (n=383) shows that 95 percent were still alive at one year and 94 percent were still receiving Letairis monotherapy. These uncontrolled observations do not allow comparison with a group not given Letairis and cannot be used to determine the long-term effect of Letairis.

In ARIES-1 and ARIES-2, a total of 261 patients received Letairis at doses of 2.5, 5 or 10 mg once daily and 132 patients received placebo. The most common adverse events that occurred at a higher frequency among Letairis-treated patients compared to placebo in the ARIES-1 and ARIES-2 studies included (placebo-adjusted frequency): peripheral edema (6 percent), nasal congestion (4 percent), sinusitis (3 percent), flushing (3 percent) and palpitations (3 percent). Most adverse drug reactions were mild to moderate and only nasal congestion was dose-dependent.

In addition to data from Phase III clinical trials, the Letairis approval is also supported by data from an uncontrolled,

open-label study of 36 patients who had previously discontinued endothelin receptor antagonists (bosentan, an investigational drug, or both) due to aminotransferase elevations greater than three times the upper limit of normal(ULN). With a median follow-up period of 13 months and with 50 percent of patients increasing the dose of Letairis to 10 mg, no patients were discontinued for aminotransferase elevations. The most common adverse events observed were peripheral edema, headache, dyspnea and flushing. The study suggests that Letairis may be an option for patients who have experienced asymptomatic aminotransferase elevations on other ERAs after aminotransferase levels have returned to normal.

"Just ten years ago, patients had few options available to combat their disease, but there is now an emerging sense of hope as awareness of this important disease grows and new treatments become available," said Rino Aldrighetti, President and CEO of the Pulmonary Hypertension Association (PHA).

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.

About Gilead(TM)Solutions

Gilead also today announced the launch of Gilead(TM)Solutions, a comprehensive set of programs designed to help patients navigate the reimbursement process for Letairis and help minimize barriers to treatment.

"Gilead is committed first and foremost to patients," said Dr. Martin. "Our hope is that this program will ensure greater access to care for PAH patients with a variety of circumstances, including the often overlooked group of patients who have some form of prescription insurance but have prohibitively high out-of-pocket expenses."

Gilead will assist most eligible privately-insured patients who have high monthly co-payments with a portion of their out-of-pocket expenses. Similarly, patients with Medicare prescription drug coverage or other government-funded insurance may receive assistance with co-payments and deductibles through two existing independent patient foundations. Some restrictions will apply. Gilead's reimbursement support team will guide patients to these resources and explain program eligibility guidelines and the amount of financial assistance available.

Similar to programs Gilead has established for patients in other disease areas, including HIV/AIDS and chronic hepatitis B, uninsured or underinsured patients will have access to reimbursement counseling and support in applying for public insurance programs for which they may qualify.

Gilead has also established a program that addresses the unique access issues that exist at the launch of a new product before formulary status and payer coverage levels are finalized. This will ensure that physicians and patients have immediate access to Letairis while Gilead's reimbursement support team works to identify appropriate financial assistance.

Gilead Solutions programs and services will only be available following enrollment in LEAP.

"Many PAH patients face significant financial barriers, such as prohibitively high co-payment expenses, while also struggling to navigate what can be a difficult treatment authorization process as well as a complicated reimbursement process, all while dealing with their PAH symptoms," said Joy Beckmann, RN, MSN, Chair, PH Resource Network, Pulmonary Hypertension Association and Senior Research Coordinator, Liu Center for Pulmonary Hypertension, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center. "It's important that adequate programs are in place to ensure that patients are not denied access to treatment for financial reasons."

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. In women who can become pregnant, pregnancy tests should be obtained monthly.

Important Safety Information

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).

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.

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

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).

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

About Letairis(TM)

Letairis(TM) (ambrisentan) is an endothelin receptor antagonist that is selective for the endothelin type-A (ET(A)) receptor. Activation of the ET(A) receptor by endothelin, a small peptide hormone, leads to vasoconstriction (narrowing of blood vessels) and cell proliferation. The clinical impact of high selectivity for ET(A) is not known. PAH is associated with elevated endothelin blood levels.

GlaxoSmithKline holds rights to commercialize ambrisentan for PAH in territories outside of the United States. A Marketing Authorisation Application (MAA) for ambrisentan was filed with the European Medicines Agency (EMEA) earlier this year.

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. 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.

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 risk that Gilead(TM)Solutions will not provide greater access to care for PAH patients with a variety of circumstances. 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, 2006 and its Report on Form 10-Q for the first quarter of 2007, 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.

Full prescribing information for Letairis is available at www.gilead.com and at www.Letairis.com.

Letairis is a trademark of Gilead Sciences, Inc.

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

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