Gilead Announces New Letairis(TM) (ambrisentan) Data for the Treatment of Patients with Pulmonary Arterial Hypertension (WHO Group 1)

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-- Long-Term Data and Integrated Subgroup Analysis in Patients with Idiopathic PAH and PAH Associated with Connective Tissue Disease Presented at the Annual Meeting of the American College of Chest

Physicians --

CHICAGO--(BUSINESS WIRE)--Oct. 23, 2007--Gilead Sciences, Inc. (Nasdaq: GILD) today announced the presentation of new data from the Phase III ARIES studies evaluating ambrisentan in patients with pulmonary arterial hypertension (PAH) at CHEST 2007, the annual meeting of the American College of Chest Physicians, taking place in Chicago, Illinois, October 20-25. Ambrisentan is an ETA-selective endothelin receptor antagonist (ERA) that was recently granted accelerated approval under the tradename Letairis(TM) (ambrisentan 5 mg and 10 mg tablets) by the U.S. Food and Drug Administration (FDA). Letairis is indicated as a once-daily treatment for PAH (WHO Group 1) in patients with WHO Class II or III symptoms to improve exercise capacity and delay clinical worsening.

"PAH is a progressive, life-threatening disease and fortunately tremendous research progress has been made over the last two decades," said Ronald J. Oudiz, MD, Associate Professor of Medicine, David Geffen School of Medicine at UCLA and Director, Liu Center for Pulmonary Hypertension, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center. "It's encouraging that new therapies such as ambrisentan have become available to treat this serious disease."

In an oral session, Dr. Oudiz presented long-term data (mean exposure = 71 weeks; maximum exposure = 148 weeks) from an integrated analysis of 383 patients with idiopathic PAH (IPAH) or PAH associated with connective tissue disease (PAH-CTD), HIV infection or anorexigen use who received at least one dose of ambrisentan (2.5, 5 or 10 mg once-daily) in one of the 12-week Phase III placebo-controlled studies (ARIES-1 or ARIES-2) or in the long-term extension study for ARIES-1 and ARIES-2 (ARIES-E). Patients who received ambrisentan in ARIES-1 or ARIES-2 remained on their current dose in ARIES-E. Patients who received placebo during previous studies were randomized to ambrisentan (ARIES-1: 5 or 10 mg; ARIES-2: 2.5 or 5 mg) in ARIES-E. Efficacy and safety assessments were measured from the time of first dose of ambrisentan. This analysis represents data available as of November 2006.

At baseline, approximately 89 percent of patients were classified as having WHO Class II or III symptoms. Baseline six-minute walk distance (6MWD) for patients in the 2.5, 5 and 10 mg groups were 350+/-87 m, 348+/-87 m and 342+/-81 m, respectively. Patients in the 2.5, 5 and 10 mg groups had baseline Borg dyspnea index (BDI) scores of 4.1+/-2.7, 3.8+/-2.3 and 2.8+/-2.1, respectively.

Improvements in the non placebo-adjusted 6MWD observed at week 12 for the 2.5, 5 and 10 mg groups (32+/-6.1 m, 36+/-5.7 m and 39+/-6.1 m, respectively) were maintained through week 48 of treatment (34+/-10.9 m, 41+/-7.9 m and 46+/-7.7 m, respectively). Improvements in WHO functional class and BDI were also maintained with long-term ambrisentan treatment. In addition, 95 percent of patients were still alive at one year of treatment with ambrisentan (95 percent CI: 93-97 percent), based on a Kaplan-Meier analysis.

The one-year risk of liver enzyme (aminotransferase) elevations greater than three times the upper limit of normal (ULN) for this Phase III study population was 2.1 percent, which was similar to the incidence observed for the placebo groups (2.3 percent) in the 12-week ARIES-1 and ARIES-2 studies. Adverse events in patients receiving ambrisentan were similar in nature to those reported in the previous 12-week placebo-controlled studies, and included peripheral edema, headache, upper respiratory tract infection and dizziness. The most common adverse event was peripheral edema which was reported to be mild or moderate.

In a second oral presentation, David Badesch, MD, Professor of Medicine and Clinical Director of the Pulmonary Hypertension Center at the University of Colorado Health Sciences Center, presented results from an integrated analysis of the 12-week ARIES-1 and ARIES-2 studies comparing the safety and efficacy of ambrisentan in patients with IPAH and PAH-CTD.

In this subgroup analysis, patients with IPAH (n=251) and PAH-CTD (n=124) received placebo, 2.5, 5 or 10 mg ambrisentan once-daily. Baseline 6MWD for patients in the IPAH placebo and ambrisentan groups were 343+/-81 m and 352+/-78 m,

respectively. Baseline 6MWD for patients in the PAH-CTD placebo and ambrisentan groups were 340+/-76 m and 332+/-84 m, respectively. Patients in the IPAH placebo and ambrisentan groups had baseline BDI scores of 4.0+/-2.2 and 3.9+/-2.2, respectively. Patients in the PAH-CTD placebo and ambrisentan groups had baseline BDI scores of 3.6+/-2.1 and 3.8+/-2.4, respectively.

Improvements in 6MWD at week 12 compared to placebo were observed for the PAH-CTD subgroup (+19+/-14.8 m; p=0.056) and IPAH subgroup (+58+/-10.8 m; p less than 0.001), but appeared greater for the IPAH subgroup. For PAH-CTD patients receiving the FDA-approved doses of 5 or 10 mg (n=62), an improvement of 25+/-14.2 m (p=0.020) in 6MWD was observed.

Improvements in dyspnea, as measured by the BDI at week 12 compared to placebo, were similar for the IPAH (-0.8+/-0.30; p=0.011) and PAH-CTD (-1.0+/-0.39; p=0.038) subgroups. WHO functional class deterioration was similar at week 12 for the IPAH and PAH-CTD subgroups receiving ambrisentan (3.6 percent and 3.7 percent, respectively) and was less than that observed in the placebo group (16.5 percent and 20.9 percent, respectively).

No patients receiving ambrisentan had aminotransferase elevations greater than three times ULN during this 12-week treatment period compared to three placebo patients who had IPAH. The incidence of peripheral edema was greater among patients receiving ambrisentan than among patients receiving placebo in both the IPAH and PAH-CTD subgroups, but the placebo-adjusted incidences were similar (6.9 percentage points and 5.8 percentage points, respectively).

"In this study, consistent trends in increased exercise capacity, decreased dyspnea and less WHO functional class deterioration were observed with ambrisentan treatment compared to placebo in both the IPAH and PAH-CTD subgroups," said Dr. Badesch. "These data indicate that ambrisentan may be a viable treatment for these patient populations."

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.

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

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

Letairis (ambrisentan) is an endothelin receptor antagonist that is selective for the endothelin type-A (ETA) receptor. Activation of the ETA receptor by endothelin, 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. 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.

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 further data from additional clinical studies

may indicate that ambrisentan is not a viable treatment for patients in both the IPAH and PAH-CTD subgroups. 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 Quarterly Reports on Form 10-Q for the first and second quarters of 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.

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

Letairis is a 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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