Gilead Submits New Drug Application To U.S. FDA for Ambrisentan for the Treatment of Pulmonary Arterial Hypertension

December 18, 2006

FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 18, 2006--Gilead Sciences, Inc. (Nasdaq:GILD) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing approval of ambrisentan (5 mg and 10 mg) for the once-daily treatment of pulmonary arterial hypertension (PAH). The application is supported by data from two Phase III clinical studies (ARIES-1 and ARIES-2) and three Phase II studies in patients with PAH.

"Current therapeutic options are limited, and there remains an urgent need for safe and effective treatments for patients with PAH," said John C. Martin, PhD, President and CEO, Gilead Sciences. "The achievement of today's milestone reflects the tremendous dedication of numerous clinical investigators and other research collaborators, all of whom share our goal of advancing new treatment options for patients suffering from PAH. This is also a testament to our Colorado-based team, who designed and managed the clinical development program for ambrisentan and whose efforts led to the completion of this new drug application."

About ARIES Pivotal Trials

In the two ARIES clinical trials, patients were randomized in a blinded fashion to receive placebo or one of two doses of ambrisentan. The trials were of identical design except for the doses of ambrisentan studied and the geographic locations of the investigative sites. Both trials were designed to enroll 186 patients (62 patients per dose group). ARIES-1 evaluated once-daily doses of 5 mg and 10 mg of ambrisentan. ARIES-2 evaluated once-daily doses of 2.5 mg and 5 mg of ambrisentan. ARIES-1 enrolled 202 patients primarily in the United States while ARIES-2 enrolled 192 patients primarily in Europe.

Approximately 400 patients from these and other studies are continuing ambrisentan treatment in long-term clinical trials.

About Ambrisentan

Ambrisentan is a non-sulfonamide, propanoic acid-class, endothelin receptor antagonist that is selective for the endothelin type-A (ETa) receptor. Endothelin is a small peptide hormone that plays a critical role in the control of blood flow and cell growth. Elevated endothelin blood levels are associated with PAH. Ambrisentan has been granted orphan drug designation for the treatment of PAH in both the United States and European Union.

Ambrisentan is an investigational compound and has not yet been determined safe or efficacious in humans.

Gilead acquired the U.S. rights to ambrisentan when it completed its acquisition of Myogen, Inc. on November 17, 2006. GlaxoSmithKline holds rights to commercialize ambrisentan outside of the United States.

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 risks related to Gilead's ability to develop and commercialize this product. For example, ambrisentan may not be approved for the doses Gilead is seeking, the safety and efficacy data from additional clinical studies may not warrant further development of this compound and initiating and completing clinical trials may take longer or cost more than expected. 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 the Gilead Annual Report on Form 10-K for the year ended December 31, 2005, 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.

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