FDA Advisory Committee Supports Use of Aztreonam for Inhalation Solution for Patients With Cystic Fibrosis

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FOSTER CITY, Calif., Dec 10, 2009 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the Anti-Infective Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) has recommended that aztreonam for inhalation solution be approved for the treatment of infections due to Pseudomonas aeruginosa (P. aeruginosa) in patients with cystic fibrosis (CF). The committee voted 15 to 2that Gilead has provided sufficient evidence of the safety and efficacy of aztreonam for inhalation solution. The panel also voted 17 to 0 that aztreonam for inhalation solution 75 mg three times daily is a correct dose and regimen.

The recommendations of the Advisory Committee are not binding but will be considered by the FDA as the agency completes its review of Gilead's application. The FDA has established a target review date, under the Prescription Drug User Fee Act (PDUFA), of February 13, 2010. In the interim, Gilead will continue to make the product available through its Expanded Access Program in the United States.

"Effectively treating infections in patients with CF is very challenging, and new treatment options are urgently needed," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "We will continue to work closely with the FDA as it completes its review of aztreonam for inhalation solution."

CF is a chronic, debilitating genetic disease that affects the respiratory and digestive systems of approximately 70,000 people worldwide. Chronic pulmonary infections due to *P. aeruginosa* are the single greatest cause of morbidity and mortality among patients with CF.

Gilead originally submitted the NDA for the potential product in November 2007. In September 2009, the product was granted conditional marketing approval in Canada and the European Union under the trade name Cayston$^{(R)}$ (aztreonam lysine 75 mg powder and solvent for nebuliser solution). Applications for marketing approval of Cayston are also pending in Australia, Switzerland and Turkey.

About Aztreonam for Inhalation Solution

Aztreonam for inhalation solution is an antibiotic candidate for people with cystic fibrosis who have *P. aeruginosa*. Aztreonam has potent *in vitro* activity against Gram-negative bacteria such as *P. aeruginosa*. Aztreonam formulated with arginine is an FDA-approved agent for intravenous administration for treating various infections. Aztreonam formulated with lysine is a proprietary formulation of aztreonam developed specifically for inhalation. It has been designated with orphan drug status in the United States and European Union.

In the United States, aztreonam for inhalation solution has not yet been determined by the FDA to be safe or efficacious in humans for its ultimate intended use.

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.

Forward-Looking Statement

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 the approval of aztreonam for inhalation solution. For example, notwithstanding the recommendation of the Anti-Infective Drugs Advisory Committee,

the FDA may not approve aztreonam for inhalation solution, which may cause Gilead considerable expense and may lead to further delays or cause Gilead to abandon further development of the product in the United States. Further, Gilead may not obtain marketing approval of aztreonam for inhalation solution in Australia, Switzerland and Turkey, where applications are also pending. In addition, safety issues may arise or the results from the clinical study may be otherwise inadequate to support full regulatory approval of aztreonam for inhalation solution in jurisdictions where conditional marketing approval was granted, such as the European Union and Canada. 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 Quarterly Report on Form 10-Q for the third quarter of 2009, 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, please call the Gilead Public Affairs Department at 1-800-GILEAD-5 (1-800-445-3235) or visit www.gilead.com.

SOURCE: Gilead Sciences, Inc.

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