European CHMP Adopts Positive Opinion for Aztreonam Lysine

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Jun. 26, 2009-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency, has adopted a positive opinion on the company's Marketing Authorisation Application for aztreonam lysine 75 mg powder and solvent for nebuliser solution (aztreonam lysine) for the suppressive therapy of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis (CF) aged 18 years and older. The opinion is for conditional approval, contingent on the successful completion of an ongoing study.

The CHMP's positive recommendation will be reviewed by the European Commission, which has the authority to approve medicinal products for use in the 27 countries of the European Union. Gilead expects the European Commission to issue its decision on the marketing authorization for aztreonam lysine later this year. Aztreonam lysine was previously reviewed by the CHMP in March and received a negative opinion, which Gilead appealed.

"We are pleased that the CHMP has recognized the potential therapeutic benefit of aztreonam lysine in addressing chronic pseudomonal airway infection – the single greatest cause of morbidity and mortality for people with cystic fibrosis," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "We look forward to delivering this new therapeutic option to patients in the European Union as quickly as possible."

Gilead has also submitted applications for marketing approval of aztreonam lysine in Australia, Canada, Switzerland and Turkey. In the United States, the U.S. Food and Drug Administration (FDA) has informed Gilead of the need to conduct an additional clinical study before the company can resubmit its New Drug Application. Gilead has two ongoing clinical studies evaluating the product among patients with CF.

About Cystic Fibrosis

Today, more than 70,000 people worldwide have cystic fibrosis. Cystic fibrosis is a chronic, debilitating genetic disease. A major characteristic of cystic fibrosis is production of abnormally thick, sticky mucus in the lungs that traps bacteria and predisposes people with cystic fibrosis to lung infections. Currently, there is no known cure for cystic fibrosis, and the goal of cystic fibrosis therapy is to control symptoms and prevent further lung damage.

About Aztreonam Lysine

Aztreonam lysine 75 mg powder and solvent for nebuliser solution is an inhaled antibiotic candidate for people with cystic fibrosis who have *P. aeruginosa*. Aztreonam formulated with arginine (Azactam®) is an approved agent for intravenous administration for treating various infections. Aztreonam lysine is a proprietary formulation of aztreonam developed specifically for inhalation. It has been designated with orphan drug status in the United States and Europe.

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 the uncertainty of when the European

Commission will issue its decision on the marketing approval of aztreonam lysine. In addition, the CHMP's positive opinion is contingent on the successful completion of an ongoing study, and there is the risk that safety issues may arise or the results from the clinical study may be otherwise inadequate to support regulatory approval of the product. Further, existing data from any ongoing clinical trials or any additional clinical trial that we may commence to satisfy FDA concerns may not support the approval of aztreonam lysine in the United States, which may cause us considerable expense and may lead to further delays or cause us to abandon further development of the product in the United States. 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 quarter ended March 31, 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.

Gilead Sciences, Inc.
Patrick O'Brien, 650-522-1936 (Investors)
Amy Flood, 650-522-5643 (Media)