

European CHMP Adopts Negative Opinion on Aztreonam Lysine

March 19, 2009 12:32 PM ET

FOSTER CITY, Calif.--(BUSINESS WIRE)--Mar. 19, 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 negative opinion on the company's Marketing Authorisation Application (MAA) for aztreonam lysine 75 mg powder and solvent for nebuliser solution (aztreonam lysine) in the European Union. Aztreonam lysine is an investigational therapy in development for people with cystic fibrosis who have pulmonary *Pseudomonas aeruginosa* (*P. aeruginosa*) infection.

"We are disappointed by the Committee's opinion, but remain committed to advancing therapies for patients with cystic fibrosis," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Chronic pseudomonal airway infection is the leading cause of morbidity and mortality among people living with cystic fibrosis, and with a limited number of treatment choices, there remains a significant unmet medical need."

Gilead will confer with European regulatory bodies to determine appropriate options to address the issues outlined in the CHMP opinion. 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 aztreonam for inhalation solution.

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 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 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 risks related to our ability to obtain marketing approval of aztreonam lysine in the European Union and the United States. For example, there is the risk that existing data from any ongoing or from any further clinical trials that we may commence to satisfy regulatory authorities' concerns will not support approval of aztreonam lysine and that this may cause Gilead to incur considerable expense, would lead to further delays or cause the company to abandon further development of the product. There are also risks that health authorities in other countries where marketing authorization applications are pending will undertake similar additional reviews which would compound the risks described above. 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, 2008, 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

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Source: Gilead Sciences, Inc.

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