

## **Gilead Receives Response From U.S. FDA on Company's Request for Formal Dispute Resolution for Aztreonam for Inhalation Solution**

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### **FDA Reiterates Position of Complete Response Letter**

FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 18, 2009-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the company has received a response from the U.S. Food and Drug Administration (FDA) to its appeal, submitted under the formal Dispute Resolution process, regarding the Agency's Complete Response Letter for its New Drug Application (NDA) for aztreonam for inhalation solution. Gilead initiated the formal Dispute Resolution process in November 2008, following receipt of the Complete Response Letter in September 2008. In its review under the Dispute Resolution process, the FDA reiterated its position outlined in the Complete Response Letter, including the need for Gilead to conduct an additional clinical study of aztreonam for inhalation solution before the company can resubmit its NDA.

Gilead has two ongoing clinical studies evaluating aztreonam for inhalation solution. The company has not yet discussed with the FDA whether or not either of these studies would be sufficient to address the FDA's requirements or whether Gilead will need to design and conduct a new study. The company will provide further updates once it has more clarity regarding timelines.

### **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 a 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 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 risk that ongoing clinical studies will not be sufficient to address the FDA's requirements and the risk that the FDA may ultimately decline to approve aztreonam for inhalation solution, even after additional data are submitted. 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, 2007 and its Quarterly Report on Form 10-Q for the first, second and third quarters of 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 (1-800-445-3235) or visit [www.gilead.com](http://www.gilead.com)*

Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.

Susan Hubbard, 650-522-5715 (Investors)

Amy Flood, 650-522-5643 (Media)