Gilead Sciences Announces Notification of ANDA Filing for Ranexa(R)

June 10, 2010 8:32 PM ET

FOSTER CITY, Calif., Jun 10, 2010 (BUSINESS WIRE) --Gilead Sciences, Inc. (Nasdaq:GILD) today announced receipt of a Paragraph IV Certification Notice Letter advising that Lupin Limited submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) requesting permission to manufacture and market a generic version of Ranexa(R) (ranolazine extended-release tablets).

In the Notice Letter, Lupin alleges that all 10 patents associated with Ranexa are invalid, unenforceable and/or will not be infringed by Lupin's manufacture, use or sale of the product described in its ANDA submission.

Gilead is currently reviewing the Notice Letter and has 45 days from the date of receipt to commence a patent infringement lawsuit against Lupin. Such a lawsuit would restrict the FDA from approving Lupin's ANDA for up to 30 months or until a district court decision that is adverse to Gilead, whichever occurs first. Ranexa is currently protected by 10 patents, which are listed in the FDA's Approved Drugs Products List and all 10 patents would need to be invalidated or expired before a generic version of Ranexa could be marketed.

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 uncertainty related to whether Gilead will file a patent infringement lawsuit against Lupin and whether such a lawsuit would be successful. 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 first quarter of 2010, 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.

Ranexa is a registered trademark of Gilead Sciences, Inc.

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.
Susan Hubbard, 650-522-5715 (Investors)
Cara Miller, 650-522-1616 (Media)