Gilead Sciences Announces Notification of ANDA Filing for Viread®

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FOSTER CITY, Calif., Jan 27, 2010 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq:GILD) today announced receipt of a Paragraph IV Certification Notice Letter advising that Teva Pharmaceuticals 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 Viread(R) (tenofovir disoproxil fumarate).

In the Notice Letter, Teva alleges that three patents associated with tenofovir disoproxil - U.S. Patent Numbers 5,922,695; 5,977,089; and 6,043,230; and one patent associated with tenofovir disoproxil fumarate - U.S. Patent Number 5,935,946 - owned by Gilead Sciences are invalid, unenforceable and/or will not be infringed by Teva'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 Teva. Such a lawsuit would restrict the FDA from approving Teva's ANDA for up to 30 months or until a district court decision that is adverse to Gilead, whichever occurs first.

Viread is currently protected by four patents, which are listed in the FDA's Approved Drug Products List, and all four patents would need to be invalidated or expired before a generic version of Viread could be marketed. The U.S. Patent & Trademark Office (PTO) confirmed the patentability of these four Viread patents in 2008.

Gilead currently has a lawsuit pending against Teva in response to Teva's attempts to seek approval for generic versions of Truvada$^{(R)}$ (emtricitabine and tenofovir disoproxil fumarate) and Atripla$^{(R)}$ (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) based on allegations that two emtricitabine patents are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of its generic product.

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 another patent infringement lawsuit against Teva and whether such a lawsuit or the lawsuit that is currently pending related to Teva's ANDA filing for Truvada and Atripla 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 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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