

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

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FOSTER CITY, Calif., Feb 07, 2011 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq: GILD) today announced receipt of a Paragraph IV Certification Notice Letter advising that Natco Pharma 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 Tamiflu^(R) (oseltamivir phosphate) 75 mg capsules.

In the Notice Letter, Natco alleges that a patent associated with Tamiflu - U.S. Patent Number 5,763,483 - owned by Gilead Sciences is invalid, unenforceable and/or will not be infringed by Natco'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 Natco. Such a lawsuit would restrict the FDA from approving Tamiflu's ANDA for up to 30 months or until a district court decision that is adverse to Gilead, whichever occurs first. Tamiflu is protected by this patent, which is listed in the FDA's Approved Drug Products List, and the patent would need to be invalidated or not infringed upon before a generic version of Tamiflu could be marketed without liability for patent infringement.

Tamiflu was invented by Gilead Sciences and licensed to F. Hoffmann-La Roche Ltd in 1996.

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 Natco 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 third 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.

Tamiflu is a registered trademark of Hoffmann-La Roche Inc.

For more information on Gilead Sciences, please visit www.gilead.com or call the Gilead Public Affairs Department at 1-800-GILEAD-5 (1-800-445-3235).

SOURCE: Gilead Sciences, Inc.

Gilead Sciences, Inc.
Patrick O'Brien, 650-522-1936 (Investors)
Cara Miller, 650-522-1616 (Media)