

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

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FOSTER CITY, Calif., Aug 19, 2010 (BUSINESS WIRE) --

Gilead Sciences, Inc. (Nasdaq:GILD) today announced receipt of a Paragraph IV Certification Notice Letter advising that Sigmapharm Laboratories, LLC 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 Hepsera^(R) (adefovir dipivoxil).

In the Notice Letter, Sigmapharm alleges that two patents associated with Hepsera - U.S. Patent Numbers 5,663,159 and 6,451,340 - owned by Gilead Sciences are invalid, unenforceable and/or will not be infringed by Sigmapharm'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 Sigmapharm. Such a lawsuit would restrict the FDA from approving Hepsera's ANDA for up to 30 months or until a district court decision that is adverse to Gilead, whichever occurs first. Hepsera is currently protected by these two patents, which are listed in the FDA's Approved Drug Products List, and both patents would need to be invalidated or not infringed upon before a generic version of Hepsera 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 Sigmapharm 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 and second quarters 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.

Hepsera 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.

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