U.S. FDA Accepts New Drug Application for Gilead's Once-Daily, Single-Tablet Quad HIV Regimen

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 23, 2011-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for the Quad, a complete single-tablet HIV regimen containing elvitegravir, cobicistat, emtricitabine and tenofovir disoproxil fumarate.

Gilead submitted the Quad NDA on October 27, 2011. The FDA has set a target review date for the Quad under the Prescription Drug User Fee Act (PDUFA) of August 27, 2012.

About the Quad

The Quad contains four Gilead compounds in a complete once-daily, single-tablet regimen: elvitegravir; cobicistat, a "boosting" agent that enables elvitegravir once-daily dosing; and Truvada® (emtricitabine/tenofovir disoproxil fumarate).

About Elvitegravir

Elvitegravir is an integrase inhibitor. Unlike other classes of antiretroviral agents, integrase inhibitors interfere with HIV replication by blocking the ability of the virus to integrate into the genetic material of human cells. Elvitegravir was licensed by Gilead from Japan Tobacco Inc. (JT) in March 2005. Under the terms of Gilead's agreement with JT, Gilead has exclusive rights to develop and commercialize elvitegravir in all countries of the world, excluding Japan, where JT retains rights.

About Cobicistat

Cobicistat is Gilead's proprietary potent mechanism-based inhibitor of cytochrome P450 3A (CYP3A), an enzyme that metabolizes drugs in the body. In addition to studying the agent as part of the Quad, Gilead is also examining cobicistat's potential in boosting commercially available HIV protease inhibitors, which are used in many HIV treatment regimens.

The Quad, elvitegravir and cobicistat are investigational products and their safety and efficacy have not yet been established.

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 Asia Pacific.

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 the FDA may not approve the Quad in the anticipated timelines or at all, and that any marketing approval, if granted, may have significant limitations on its use. Further, even if approved, Gilead may not be able to successfully commercialize the Quad and may make a strategic decision to discontinue development of the Quad if, for example, the market for the product fails to materialize as expected. 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 quarter ended September 30, 2011, 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.

U.S. full prescribing information for Truvada is available at www.Truvada.com.

Truvada is a trademark of Gilead Sciences, Inc.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com or call Gilead Public

Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

Source: Gilead Sciences, Inc.

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