Gilead Submits New Drug Application to U.S. FDA for Once-Daily, Single-Tablet "Quad" HIV Regimen

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- Product Would Be Gilead's Third Complete HIV Regimen and the First toContain an Integrase Inhibitor -

FOSTER CITY, Calif., Oct 27, 2011 (BUSINESS WIRE) --

Gilead Sciences, Inc. (Nasdaq: GILD) announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing approval of the "Quad", a complete single-tablet regimen of elvitegravir, cobicistat, emtricitabine and tenofovir disoproxil fumarate for the treatment of HIV-1 infection in adults. If approved, the Quad would be the only once-daily, single-tablet regimen containing an integrase inhibitor.

"We continue to dedicate our HIV research and development efforts to advancing single-tablet regimens that address important patient needs," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Based on data from our pivotal studies, we believe that the Quad has the potential to be an important new treatment option for people living with HIV, and we are pleased to have reached this significant milestone less than six weeks after the unblinding of the second pivotal Phase 3 study."

The NDA is supported by 48-week data from two pivotal Phase 3 studies in which the Quad met its primary objective of non-inferiority as compared to Atripla(R) (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) (Study 102) and to a regimen containing ritonavir-boosted atazanavir (Study 103). Complete data from the Quad pivotal studies will be presented at a scientific conference in 2012. The NDA is also supported by Chemistry, Manufacturing and Controls (CMC) information on the individual components of the Quad and the co-formulated single-tablet regimen.

The first single-tablet regimen for HIV, Atripla, was approved in 2006 and is marketed by Gilead and Bristol-Myers Squibb in the United States. The company's second single-tablet regimen, Complera(R) (emtricitabine/rilpivirine/tenofovir disoproxil fumarate), which combines Gilead's Truvada(R) (emtricitabine/tenofovir disoproxil fumarate) and Tibotec Pharmaceuticals' rilpivirine, was approved in the United States in August 2011.

About the Quad

The Quad contains four Gilead compounds in a complete once-daily, single-tablet regimen: elvitegravir, an integrase inhibitor; cobicistat, a "boosting" agent that enables elvitegravir once-daily dosing; and Truvada.

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 and other regulatory agencies may not approve the Quad, 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 June 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

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

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

Truvada and Complera are registered trademarks of Gilead Sciences, Inc. or its related companies.

Atripla is a registered trademark of Bristol-Myers Squibb & Gilead Sciences, LLC.

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.

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