Gilead Submits New Drug Application to U.S. FDA for Boosting Agent Cobicistat

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Jun. 28, 2012-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing approval of cobicistat, a pharmacoenhancing or "boosting" agent that increases blood levels of certain commercially available protease inhibitors, including atazanavir and darunavir, in order to enable once-daily dosing. Cobicistat is also a component of the Quad once-daily single tablet regimen for HIV, which is currently under U.S. and European regulatory review for treatment-naïve adult patients.

"With today's filing, Gilead's series of U.S. and European regulatory filings for the Quad and its investigational components is complete," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "We will continue to work with regulatory authorities to bring these important new therapies to people living with HIV."

The NDA for cobicistat is supported by 48-week data from a pivotal Phase 3 study (Study 114) in which cobicistat met its primary objective of non-inferiority to ritonavir when both agents were administered with a background regimen of atazanavir sulfate plus Truvada® (emtricitabine and tenofovir disoproxil fumarate). The NDA is also supported by pharmacokinetic data demonstrating that cobicistat boosts blood levels of atazanavir and darunavir similar to ritonavir.

Gilead entered into an agreement with Janssen R&D Ireland in June 2011 for the development of a fixed-dose combination of cobicistat and darunavir. In October 2011, Gilead announced an agreement with Bristol-Myers Squibb to develop a fixed-dose combination of cobicistat and atazanavir. Subject to regulatory approval, Janssen and Bristol-Myers Squibb will be responsible for the formulation, manufacturing, registration, distribution and worldwide commercialization of the cobicistat and darunavir fixed-dose combination and the cobicistat and atazanavir fixed-dose combination, respectively.

About Cobicistat

Cobicistat is Gilead's proprietary potent mechanism-based inhibitor of cytochrome P450 3A (CYP3A), an enzyme that metabolizes drugs in the body. Unlike ritonavir, cobicistat acts only as a pharmacoenhancer and has no antiviral activity.

About the Quad

The Quad contains four Gilead compounds in a complete once-daily, single tablet regimen: elvitegravir 150 mg, an integrase inhibitor; cobicistat 150 mg, a "boosting" agent that enables elvitegravir once-daily dosing; and Truvada (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg).

Cobicistat, elvitegravir and the Quad 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 FDA and other regulatory agencies may not approve cobicistat or any co-formulations containing cobicistat, or the Quad, and that any marketing approvals, if granted, may have significant limitations on their use. Further, even if approved, Gilead may not be able to successfully commercialize these products, and may make a strategic decision to discontinue their development if, for example, the market for the products 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 March 31, 2012, 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 registered trademark of Gilead Sciences, Inc.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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