Gilead Submits New Drug Application to U.S. FDA for HIV Integrase Inhibitor Elvitegravir for Treatment-Experienced Patients

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Elvitegravir Also a Component of Quad Single Tablet Regimen, Currently Under Regulatory Review for Patients New to Therapy

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jun. 27, 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 elvitegravir, an integrase inhibitor for the treatment of HIV-1 infection in treatment-experienced adults. Elvitegravir is also a component of Gilead’s once-daily Quad single tablet regimen, which is currently under U.S. and European regulatory review for treatment-naïve adult patients.

The NDA for elvitegravir is supported by 96-week data from a pivotal Phase 3 study (Study 145) in which elvitegravir (150 mg or 85 mg) dosed once daily was non-inferior to the integrase inhibitor raltegravir (400 mg) dosed twice daily, each administered with a background regimen that included a fully active ritonavir-boosted protease inhibitor and a second antiretroviral.

About Elvitegravir

Elvitegravir is a member of the integrase inhibitor class of antiretroviral compounds. Unlike other classes, 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 the Quad

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

Elvitegravir, cobicistat 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 elvitegravir, 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.


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](http://www.gilead.com), follow Gilead on Twitter ([@GileadSciences](https://twitter.com/GileadSciences)) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

Source: Gilead Sciences, Inc.

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