Gilead Receives Complete Response Letters from U.S. Food and Drug Administration for Elvitegravir and Cobicistat

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 29, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the company has received Complete Response Letters from the U.S. Food and Drug Administration (FDA) for its New Drug Applications (NDAs) for elvitegravir and cobicistat for use as part of HIV treatment regimens.

In its communications, FDA states that it cannot approve the applications in their current forms. The letters state that during recent inspections, deficiencies in documentation and validation of certain quality testing procedures and methods were observed. Gilead is working with FDA to address the questions raised in the Complete Response Letters and move the applications forward.

Elvitegravir and cobicistat are also components of Gilead's once-daily single tablet HIV-1 regimen Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), which was approved by FDA in August 2012 for treatment-naïve adults. This regulatory action does not affect the marketing authorization or continued use of Stribild.

Gilead submitted its NDAs for elvitegravir and cobicistat in June 2012. Marketing applications are also pending in Europe.

About Elvitegravir

Elvitegravir is a member of the integrase inhibitor class of antiretroviral compounds. Integrase inhibitors block the ability of HIV 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. Unlike ritonavir, cobicistat acts only as a pharmacoenhancing or "boosting" agent and has no antiviral activity.

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 we may be unable to remedy the deficiencies cited by the FDA in the Complete Response Letters on a timely basis and that our inability to address those deficiencies could adversely impact currently marketed products and products in development. There is also the risk that health authorities in other countries where applications are pending will undertake similar additional reviews which could delay the approval of such products in those countries. 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 Annual Report on Form 10-K for the year ended December 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 Stribild is available at www.gilead.com.

Stribild 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.

Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.
Patrick O’Brien, 650-522-1936 (Investors)
Erin Rau, 650-522-5635 (Media)