Gilead Sciences' New Drug Applications for Cobicistat and Elvitegravir for HIV Therapy Accepted by U.S. FDA

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-- Final FDA Decisions Anticipated by October 3 and 4, 2014 --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 21, 2014-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's refiling of two New Drug Applications (NDA) for cobicistat, a pharmacoenhancing or "boosting" agent that increases blood levels of the protease inhibitors atazanavir and darunavir to enable once-daily dosing of these medicines in HIV therapy, and elvitegravir, an integrase inhibitor for the treatment of HIV-1 infection in treatment-experienced adults. The FDA has set target review dates under the Prescription Drug User Fee Act (PDUFA) of October 3, 2014 for cobicistat and October 4, 2014 for elvitegravir.

Gilead submitted NDAs for cobicistat and elvitegravir in June 2012. In April 2013, the company received Complete Response Letters from the FDA. In its communications, the agency stated that it could not approve the cobicistat and elvitegravir applications in their current forms, citing deficiencies in documentation and validation of certain quality testing procedures and methods that were observed during inspections. Gilead has worked with the FDA to address the questions raised in the Complete Response Letters.

Cobicistat and elvitegravir are components of Gilead's Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), a once-daily single tablet regimen for the treatment of HIV-1 infection. Stribild was approved in the United States in August 2012.

Cobicistat is approved under the tradename Tybost® and elvitegravir is approved under the tradename Vitekta® in Europe, Canada and Australia.

About Cobicistat and Elvitegravir

Cobicistat is a cytochrome P450 3A (CYP3A) inhibitor. It boosts blood levels of the HIV protease inhibitors atazanavir and darunavir by suppressing CYP3A, an enzyme that metabolizes these drugs in the body. Cobicistat acts only as a pharmacokinetic enhancer and has no antiviral activity.

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 as a single agent in all countries of the world, excluding Japan, where JT retains rights.

Cobicistat and elvitegravir are investigational products in the United States 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 and South 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 risks related to the fact that the FDA may not approve elvitegravir or cobicistat in the currently anticipated timelines or at all. In addition, any marketing approvals, if granted, may have significant limitations on their use. Further, the FDA may not be satisfied with the responses Gilead provided in connection with the Complete Response Letters. 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, 2013, 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.

EU Summary of Product Characteristics for Tybost and Vitekta are available at http://www.ema.europa.eu.

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

Tybost, Stribild and Vitekta are registered trademarks 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.

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