European CHMP Adopts Positive Opinion for Eviplera(R), a Once-Daily Single-Tablet Regimen for the Treatment of HIV Infection

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FOSTER CITY, Calif., Sep 23, 2011 (BUSINESS WIRE) --

Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency, has adopted a positive opinion on the company's Marketing Authorisation Application for the once-daily single-tablet regimen, Eviplera(R), combining Gilead's Truvada(R) (emtricitabine and tenofovir disoproxil (as fumarate)) with Tibotec Pharmaceuticals' non-nucleoside reverse transcriptase inhibitor Edurant(R) (rilpivirine (as hydrochloride)) for the treatment of HIV-1 infection in antiretroviral-naïve adults with a viral load less than or equal to 100,000 HIV-1 RNA copies/mL.

The CHMP's positive recommendation will be reviewed by the European Commission, which has the authority to approve medicinal products for use in the 27 countries of the European Union (EU). Gilead expects the European Commission to issue its decision on the marketing authorization for the Eviplera single-tablet regimen later this year.

"There is a need for the simplification of treatment regimens featuring co-formulated, fixed-dose medicines as patients stay on therapy longer," said John C. Martin, PhD, Chairman and Chief Executive Officer, Gilead Sciences. "We are pleased to move one step closer to making this potentially important new simplified treatment option available to physicians and patients in Europe."

The regulatory filing for the Eviplera single-tablet regimen is supported by 48-week data from two Phase 3 double-blind, active controlled, randomized studies (ECHO and THRIVE) conducted by Tibotec evaluating the safety and efficacy of rilpivirine compared to efavirenz in treatment-naïve HIV-1 infected adults. Both arms of the studies were administered with a background regimen, in which the majority of patients in the rilpivirine arm received Truvada. A bioequivalence study conducted by Gilead demonstrated that the co-formulated single-tablet regimen achieved the same levels of medication in the blood as emtricitabine plus rilpivirine plus tenofovir disoproxil fumarate.

Gilead first entered into a license and collaboration agreement with Tibotec for the development and commercialization of the Eviplera single-tablet regimen in July 2009. The product received regulatory approval from the U.S. Food and Drug Administration under the trade name Complera(TM) (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) in August 2011.

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. These risks include the uncertainty of when the European Commission will issue its decision on the marketing approval of Eviplera, and that marketing approval, if granted, may have significant limitations on its use. 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 Complera is available at www.Complera.com.

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

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

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

EU Summary of Product Characteristics for Truvada, Viread and Emtriva are available at http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp

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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