Gilead Finalizes Selection of Bioequivalent Formulation for the Fixed-Dose Regimen of Truvada(R) and Tibotec Pharmaceuticals' TMC278

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- Gilead Anticipates Filing for Regulatory Approval of the Fixed-dose Combination Following Validation of the TMC278 New Drug Application -

FOSTER CITY, Calif., Apr 27, 2010 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq:GILD) announced today it has obtained data supporting bioequivalence of a formulation of the fixed-dose combination of Truvada(R) (emtricitabine and tenofovir disoproxil fumarate) and Tibotec Pharmaceuticals' investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) TMC278 (rilpivirine hydrochloride, 25 mg). A bioequivalence study is required to demonstrate that a co-formulated product results in the same levels of medication in the blood as achieved when the individual products are dosed simultaneously as separate pills. Gilead anticipates submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the fixed-dose combination following validation of the TMC278 NDA.

Johnson & Johnson, which owns Tibotec Pharmaceuticals, announced last week that the two pivotal Phase III studies evaluating TMC278 as a treatment for HIV in treatment-naive patients met the primary efficacy objective. In addition, the company announced plans to present the data in full at an upcoming HIV conference, and that submission of TMC278 for regulatory review is on track for the third quarter of this year.

The fixed-dose single-tablet combination of Truvada and TMC278 is an investigational product and the 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 Australia.

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 Gilead's ability to file for regulatory approval for the fixed-dose combination in the timelines currently anticipated. Regulatory agencies may not approve the fixed-dose combination for the treatment of HIV, and marketing approval, if granted, may have significant limitations on its use. In addition, future discussions with regulatory agencies may impact the amount of data needed and timelines for review, which may differ materially from Gilead's current projections. Further, safety and efficacy data from additional clinical studies may not warrant further development of this fixed-dose combination and as a result, the fixed-dose combination may never be successfully commercialized. 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. Gilead directs readers to its Annual Report on Form 10-K for the year ended December 31, 2009. Gilead claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. 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 or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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