Gilead Sciences Announces Agreement With Tibotec Pharmaceuticals to Develop and Commercialize New Fixed-Dose Combination of Truvada(R) and TMC278
-- Product Would Represent Second Truvada-Based Complete Fixed-Dose Regimen --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 16, 2009-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that it has entered into a license and collaboration agreement with Tibotec Pharmaceuticals for the development and commercialization of a new once-daily fixed-dose antiretroviral regimen containing Gilead's Truvada® (emtricitabine and tenofovir disoproxil fumarate) and Tibotec's investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) TMC278 (rilpivirine hydrochloride, 25 mg) for treatment-naïve HIV-infected individuals.

Fixed-dose combinations contain multiple medicines formulated into one tablet and help to simplify HIV therapy.

"Gilead and Tibotec share a strong focus on bringing safe and effective treatment options to people living with HIV/AIDS," said John C. Martin, PhD, Chairman and Chief Executive Officer, Gilead Sciences. "Fixed-dose regimens have become the standard of care as HIV treatment has evolved toward more simplified regimens for patients. We are very pleased to collaborate with Tibotec and look forward to advancing this new fixed-dose product."

Subject to regulatory approval, Gilead will assume the lead role in the manufacturing, registration, distribution and commercialization of the fixed-dose combination of Truvada and rilpivirine worldwide, excluding the developing world and Japan. Tibotec will be responsible for the commercialization of rilpivirine as a stand-alone product and will hold rights to co-promote the fixed-dose combination in these territories. The companies will also work towards an agreement to make the fixed-dose combination of Truvada and rilpivirine available in the developing world.

If approved, the new product would become the second complete antiretroviral treatment regimen for HIV available in a single tablet taken once daily. The first and only such therapy available today, Atripla® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), was approved by the U.S. Food and Drug Administration (FDA) in 2006. Both Atripla and the new fixed-dose combination contain a nucleoside reverse transcriptase inhibitor (NRTI) backbone of Truvada.

Current HIV treatment guidelines issued by the U.S. Department of Health and Human Services list emtricitabine and tenofovir (the components of Truvada) in combination with an NNRTI or a protease inhibitor as a preferred regimen for patients initiating therapy. Tibotec is currently studying the combination of Truvada and rilpivirine in Phase III clinical trials.

About Rilpivirine

Rilpivirine is an investigational non-nucleoside reverse transcriptase inhibitor being developed by Tibotec Pharmaceuticals. Two Phase III trials for rilpivirine are currently being conducted in the United States, Canada, Africa, Asia, Europe and South America. As an investigational agent, the safety and efficacy of rilpivirine, in combination with other antiretroviral agents, has not yet been established in humans.

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.

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 whether ongoing clinical trials for rilpivirine will be successful and whether rilpivirine will receive regulatory approval, our ability to formulate the combination product or to perform clinical trials and our ability to obtain FDA and other regulatory approvals. As a result, the combination product may never be successfully commercialized. Further, the parties may make a strategic decision to discontinue development of the combination product if, for example, we are unable to successfully formulate the fixed-dose combination or the market for the product 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, 2009, 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.
Atripla is a registered trademark of Bristol-Myers Squibb & Gilead Sciences, LLC.

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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Return to Press Releases