Gilead Sciences Announces Agreement With Tibotec Pharmaceuticals to Develop and Commercialize a New Fixed-Dose Combination of Cobicistat and Prezista(R)

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FOSTER CITY, Calif., Jun 28, 2011 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that it has entered into a license agreement with Tibotec Pharmaceuticals for the development and commercialization of a new fixed-dose antiretroviral combination product containing Gilead's cobicistat and Tibotec's protease inhibitor Prezista® (darunavir). Cobicistat is an investigational pharmacoenhancing or "boosting" agent that increases blood levels of certain HIV medicines to allow for once-daily dosing. Prezista is indicated in the United States for the treatment of HIV-infected individuals and is co-administered with ritonavir in combination with other antiretroviral agents.

"Cobicistat's formulation and clinical profile provides us with the flexibility to co-formulate and develop new combination products, including the potential to co-formulate with protease inhibitors such as Prezista," said Norbert W. Bischofberger, PhD, Gilead's Executive Vice President, Research and Development and Chief Scientific Officer. "This agreement represents another important step forward in our commitment to developing simplified treatment regimens that can help address the individual needs of people living with HIV."

Subject to regulatory approval, Tibotec will be responsible for the formulation, manufacturing, registration, distribution and commercialization of the cobicistat and Prezista fixed-dose combination worldwide. Gilead retains sole rights for the manufacture, development and commercialization of cobicistat as a stand-alone product and for use in combination with other agents.

In connection with this agreement, the companies are also negotiating terms for the development and commercialization of a future single-tablet regimen (STR) combining Prezista with Gilead's Emtriva® (emtricitabine), which is approved for the treatment of HIV infection on a worldwide basis, and its investigational agents GS 7340 and cobicistat. Gilead would be responsible for the development and commercialization of the new STR on a worldwide basis. The agreement to develop the fixed-dose combination of cobicistat and Prezista iscontingent uponthe signing of the agreement to develop the Emtriva, GS 7340, cobicistat and Prezista STR.

About Cobicistat

Gilead is evaluating cobicistat in a pivotal Phase III program, both as a stand-alone boosting agent for protease inhibitors, in this case with once-daily atazanavir, as well as part of the all Gilead investigational fixed-dose single-tablet "Quad" regimen of elvitegravir, cobicistat and Truvada® (emtricitabine/tenofovir disoproxil fumarate) for the treatment of HIV infection.

Cobicistat is Gilead's proprietary potent mechanism-based inhibitor of cytochrome P450 3A (CYP3A), an enzyme that metabolizes drugs in the body.

About GS 7340

GS 7340, Gilead's investigational anti-HIV agent in Phase Ib studies, is a prodrug of tenofovir, the active agent in the company's HIV drug Viread® (tenofovir disoproxil fumarate). A GS 7340/Emtriva tablet has been developed and entered a human bioavailability study earlier this year.

Cobicistat and GS 7340 are investigational products and have not yet been determined safe or efficacious 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 Asia Pacific.

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

cobicistat will be successful and the ability to formulate cobicistat with other agents, including darunavir. In addition, safety and efficacy data from additional clinical trials may not warrant further development of cobicistat or the combination product, the FDA and other regulatory approvals may not approve cobicistat as a stand-alone product or in any combination product, and marketing approval, if granted, may have significant limitations on its use. As a result, the combination product may never be successfully commercialized. The parties may make a strategic decision to discontinue development of the combination product if, for example, Tibotec is unable to successfully formulate the combination product or the market for the product fails to materialize as expected. Further, Gilead and Tibotec may never reach agreement on the terms for the development of a STR of darunavir, Emtriva, GS 7340 and cobicistat, and the clinical trials of GS 7340 may not be successful. As a result, the agreement to develop the fixed-dose combination of cobicistat and darunavir may terminate. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the 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, 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.

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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