

## **Gilead Sciences Finalizes Agreement with Tibotec Pharmaceuticals to Develop and Commercialize a Single-Tablet Regimen of Prezista(R) with Emtriva(R), GS 7340 and Cobicistat**

November 15, 2011 4:07 PM ET

FOSTER CITY, Calif., Nov 15, 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 single-tablet regimen combining Prezista<sup>(R)</sup> (darunavir) with Gilead's Emtriva<sup>(R)</sup> (emtricitabine); its investigational agent GS 7340, a novel prodrug of tenofovir; and cobicistat, a pharmacoenhancer.

"We are pleased to once again be partnering with Tibotec to advance and simplify HIV treatment for patients," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "This is the first time we are developing a protease inhibitor-containing single-tablet regimen, and we're able to do that based on the small milligram size of GS 7340, which is less than one tenth of the amount of the 300 mg of tenofovir disoproxil fumarate contained in Viread and Truvada."

Gilead will be responsible for the formulation, manufacturing, registration and, subject to regulatory approval, distribution and commercialization of the single-tablet regimen worldwide. Tibotec will have the right to co-detail the single-tablet regimen in certain major markets.

Gilead first entered into a collaboration with Tibotec in July 2009 for the development and commercialization of a single-tablet regimen combining Gilead's Truvada<sup>(R)</sup> (emtricitabine/tenofovir disoproxil fumarate) and Tibotec's Edurant<sup>(R)</sup> (rilpivirine). The product was approved under the trade name Complera<sup>(R)</sup> (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) in the United States in August 2011.

On June 28, 2011, Gilead announced a licensing agreement with Tibotec for the development of a fixed-dose combination containing Prezista and cobicistat, which was contingent upon the signing of the agreement to develop the Prezista, Emtriva, GS 7340 and cobicistat single-tablet regimen. Both agreements have now been finalized. Subject to regulatory approval, Tibotec will be responsible for the formulation, manufacturing, registration, distribution and commercialization of the Prezista and cobicistat fixed-dose combination worldwide.

### **About Cobicistat**

Gilead is evaluating cobicistat in three separate pivotal Phase 3 studies, both as a stand-alone boosting agent for once-daily atazanavir, as well as part of the all Gilead fixed-dose single-tablet Quad regimen of elvitegravir, cobicistat and Truvada for the treatment of HIV infection.

### **About GS 7340**

GS 7340, Gilead's investigational anti-HIV agent, is a novel prodrug of tenofovir, the active agent in the company's HIV drug Viread<sup>(R)</sup> (tenofovir disoproxil fumarate). Phase 2a dose-ranging studies have identified a dose that is ten times lower than Viread and provides greater antiviral efficacy. Gilead expects to initiate a Phase 2 study of GS 7340 early next year.

Cobicistat, GS 7340 and the Quad are investigational products 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 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 and GS 7340 will be successful and Gilead's ability to formulate cobicistat and GS 7340 with other agents, including darunavir. In addition, safety and efficacy data from clinical trials may not warrant further development of cobicistat, GS 7340 or the single-tablet regimen. Further, the regulatory authorities may not approve cobicistat and GS 7340 as stand-alone products or in any combination product, and marketing approval, if granted, may have significant limitations on its use. As a result, cobicistat, GS 7340 and the single-tablet regimen may never be successfully commercialized. The parties may make a strategic decision to discontinue development of the combination product if, for example, Gilead is unable to successfully formulate the single-tablet regimen 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. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 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.

*Complera, Emtriva, Truvada and Viread are registered trademarks of Gilead Sciences, Inc.*

*Prezista and Edurant are registered trademarks of Tibotec, Inc.*

*For more information on Gilead Sciences, please visit the company's website at [www.gilead.com](http://www.gilead.com) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.*

SOURCE: Gilead Sciences, Inc.

Gilead Sciences, Inc.  
Susan Hubbard, 650-522-5715 (Investors)  
Erin Rau, 650-522-5635 (Media)