Gilead Announces Amended Agreements With Janssen to Develop and Commercialize Tenofovir Alafenamide-Based Single Tablet Regimens for HIV Treatment

December 29, 2014

FOSTER CITY, Calif.--(BUSINESS WIRE)--Dec. 29, 2014-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced an expansion to its agreement with Janssen R&D Ireland for the development and commercialization of a new once-daily single tablet regimen containing Gilead's tenofovir alafenamide (TAF) and emtricitabine, and Janssen's rilpivirine. The original agreement was established in 2009 for the development and commercialization of Complera®, marketed as Eviplera® in the European Union, which combines tenofovir disoproxil fumarate, emtricitabine and rilpivirine in a once-daily tablet. Gilead will initiate Phase 3 studies of emtricitabine/rilpivirine/TAF in the coming months. Pending the product's approval, Gilead will be responsible for the manufacturing, registration, distribution and commercialization of the regimen in most countries, while Janssen will distribute in approximately 17 markets.

TAF is a novel nucleotide reverse transcriptase inhibitor that has demonstrated high antiviral efficacy at a dose 10 times lower than Gilead's Viread ® (tenofovir disoproxil fumarate), as well as an improved renal and bone safety profile.

"We believe that TAF's efficacy and safety advantages may make it a strong backbone of new fixed-dose combinations and single tablet regimens," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Gilead is pleased to continue its collaboration with Janssen to bring improved treatment options to patients living with HIV."

Gilead and Janssen also have amended a licensing agreement for the development and commercialization of a once-daily single tablet regimen for HIV containing Gilead's TAF, emtricitabine and cobicistat, and Janssen's darunavir. Under the amended agreement, Janssen will be responsible for further development of the regimen and, subject to regulatory approval, the manufacturing, registration, distribution and commercialization of the product worldwide.

Separate to the Janssen agreements, Gilead is advancing its own TAF-based single tablet regimen containing elvitegravir, cobicistat, emtricitabine and TAF. The company announced on November 6, 2014, it filed for regulatory approval in the United States.

TAF and TAF-based regimens are investigational products in the United States 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. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

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 whether ongoing clinical trials of TAF-based combinations will be successful and Gilead's ability to coformulate new single tablet regimens containing TAF, emtricitabine and rilpivirine, and TAF, emtricitabine, cobicistat and darunavir. In addition, Gilead and Janssen may make a strategic decision to discontinue development of the TAF combination products if, for example, the market for the products fails to materialize as expected. As a result, the agreements may terminate. Further, regulatory authorities may not approve TAF-based regimens, and marketing approvals, if granted, may have significant limitations on their use. As a result, TAF combination products 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. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, 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 and Viread is available at www.gilead.com.

Complera, Eviplera and Viread are registered trademarks of Gilead Sciences, Inc. or its related companies.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

Source: Gilead Sciences, Inc.

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