Gilead Expands Access Program for Medications in Developing World

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- Licenses Rights to HIV Pipeline Products to Indian Partners -
- First Company to Enter Licensing Agreement with Medicines Patent Pool -

LONDON & HYDERABAD, India, Jul 12, 2011 (BUSINESS WIRE) -- Gilead Sciences, Inc. (Nasdaq:GILD) announced today an expansion of its global access program in an effort to provide accelerated access to Gilead medicines for the treatment of HIV/AIDS. The changes announced today include new licensing terms with four India-based drug manufacturers - Hetero Drugs Ltd., Matrix Laboratories Ltd., Ranbaxy Laboratories Ltd. and Strides Arcolab Ltd. - for three drugs which are currently in late-stage clinical development. These Indian partners have played an active role in supplying treatment to patients in the developing world. In addition, Gilead is the first pharmaceutical company to enter a licensing agreement with the Medicines Patent Pool Foundation (the Pool).

The expanded licensing terms grant to the company's Indian partners and the Pool future rights to elvitegravir, an investigational integrase inhibitor; cobicistat, an investigational antiretroviral boosting agent; and the "Quad," which combines four Gilead HIV medicines in a once-daily, single-tablet regimen. Gilead licensed rights to commercialize elvitegravir from Japan Tobacco (JT), and JT is working in close partnership with Gilead to ensure future access to elvitegravir in the developing world.

"Gilead is proud to engage in innovative partnerships to expand access for patients in the developing world, and we welcome new opportunities to work with Indian manufacturers and the Medicines Patent Pool," said Gregg H. Alton, Gilead's executive vice president for corporate and medical affairs. "Our goal is to ensure that as new Gilead HIV therapies are developed and approved, low-cost versions will be rapidly accessible in developing countries without delay."

Licensing agreements are a cornerstone of Gilead's efforts to increase access to the company's therapies in the developing world. Since 2006, when Gilead initially established licensing agreements with Indian partners, the lowest available price of a Gilead antiretroviral has decreased to US$6.15 per patient per month, or 21 cents per day. Today, more than 1.1 million patients in developing countries receive Gilead HIV medication produced by Indian partners.

Gilead also makes branded versions of its HIV medicines available at significantly discounted prices (at the company's cost of manufacturing) in developing countries. A total of 1.6 million patients in developing countries are currently receiving either generic or branded Gilead HIV medicines - representing nearly one-fourth of the 6.6 million patients receiving HIV therapy in the developing world. Gilead's regional distribution partners help to manage pharmacovigilance and medical education efforts, and work to secure product registration in individual countries [for a full report on registration status visit http://www.gilead.com].

Medicines Patent Pool

Gilead has granted the Medicines Patent Pool similar licensing terms as its Indian partners. The Pool, established in July 2010 with the support of UNITAID, is working to collaborate with a number of pharmaceutical companies to expand global access to quality, low-cost antiretroviral therapy through the licensing of patents. Companies interested in producing generic versions of Gilead medicines for developing countries will be able to approach the Patent Pool to negotiate licensing terms.

"The Medicines Patent Pool is a creative new approach for increasing access to treatment by facilitating access to IP on essential medicines, and we appreciate Gilead's willingness to be engaged and involved with us from the beginning," said Ellen 't Hoen, executive director, Medicines Patent Pool Foundation. "We look forward to working together to expand access to much-needed antiretrovirals and fixed-dose combinations for patients in the developing world. Our expectation now is that other companies will follow Gilead's lead and join the Pool."

Global Access Licensing Terms

Gilead's original licensing agreements provided Indian manufacturers with non-exclusive rights to produce active pharmaceutical ingredient and finished product and sell generic versions of Gilead's HIV medicines Viread(R) (tenofovir disoproxil fumarate, or TDF) and Truvada(R) (emtricitabine/tenofovir disoproxil fumarate) in 95 developing countries, including India.

The expanded agreements include future rights to produce and sell generic versions of three Gilead HIV therapies, if and when they are approved. Elvitegravir, cobicistat and the Quad are investigational products and have not yet been determined safe or efficacious in humans. The agreements also allow the sale of Viread and Truvada in an additional 16 countries, and also allow Viread to be produced and sold for the treatment of chronic hepatitis B in the expanded territory.

Licensees will receive a complete technology transfer of the Gilead manufacturing process to support their efforts to obtain local regulatory approvals and scale up production as soon as possible following U.S. Food and Drug Administration approval of the pipeline products covered under the agreement.

"India's pharmaceutical industry has the scientific expertise and large-scale production capacity that are critical for addressing the challenges of the HIV epidemic - both in India and around the world," said Rajiv Malik, Director, Matrix Laboratories Ltd. and COO, Mylan Inc, which was one of the first partners to sign an expanded licensing agreement with Gilead. "We are pleased to expand our innovative collaboration with Gilead as we seek to help more individuals living with HIV in resource-limited countries."

Under the terms of the agreements, licensees are allowed to establish their own price and will pay a royalty on sales of finished product, which supports product registration, medical education and training, safety monitoring and other critical activities. In an effort to accelerate the development of pediatric formulations of HIV medicines and address growing treatment needs among children, Gilead will waive royalty payments on any pediatric formulations of Viread, Truvada or pipeline products that are successfully developed and brought to market.

Global Impact of HIV and Hepatitis B

According to the World Health Organization, significant progress has been made in recent years in increasing access to HIV treatment in the developing world. Between 2002 and 2010, the number of people in developing countries receiving antiretroviral therapy increased by more than 2,100 percent, from fewer than 300,000 to 6.6 million. However, HIV treatment needs continue to grow, with as many as 15 million people requiring treatment now, and an estimated 30 million expected to require treatment within the next five years.

Chronic hepatitis B is a common and potentially fatal liver disease caused by the hepatitis B virus (HBV), which is up to 100 times more easily transmitted than HIV. Approximately 350 million people are estimated to be chronically infected with HBV worldwide.

Tenofovir disoproxil fumarate, the active ingredient of Viread, is a prodrug of tenofovir. Tenofovir was discovered through a collaborative research effort between Dr. Antonin Holy, Institute for Organic Chemistry and Biochemistry, Academy of Sciences of the Czech Republic (IOCB) in Prague and Dr. Erik DeClercq, Rega Institute for Medical Research, Katholic University in Leuven, Belgium.

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.

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 that the U.S. Food and Drug Administration and other regulatory approvals may not approve elvitegravir, cobicistat or the Quad for the treatment of HIV, and marketing approval, if granted, may have significant limitations on its use. 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, 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.

Truvada and Viread are registered trademarks 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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