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Mylan Named as Gilead's Exclusive Branded Medicines Business Partner for India

PITTSBURGH and MUMBAI, India, Jan. 31, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its India-based subsidiary Mylan Pharmaceuticals Private Limited has been named Gilead Sciences, Inc.'s (Nasdaq: GILD) exclusive branded medicines business partner for India.

Under the agreement, Mylan will market and distribute in India Gilead's:

- HIV therapies Viread[®] (tenofovir disoproxil fumarate), Truvada[®] (emtricitabine/tenofovir disoproxil fumarate) and the newer single tablet regimen Stribild[®] (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg)
- AmBisome[®] (amphotericin B liposome for injection), a treatment for life-threatening, systemic fungal infections, which is also used to treat the parasitic disease visceral leishmaniasis
- Viread[®] for its indication as a treatment for chronic hepatitis B virus (HBV) infection.

Gilead has partnered with Mylan since 2006, granting the company rights to manufacture and sell their own generic versions of licensed Gilead HIV therapies in India and up to 111 developing world countries where the HIV epidemic affects millions of individuals. Mylan will continue to maintain these rights, in addition to those in this new agreement.

Mylan CEO Heather Bresch commented, "This further extension of our collaboration with Gilead builds off of our existing successful partnership manufacturing and supplying high-quality, cost-effective generic antiretroviral therapy for those in resource challenged countries, delivering on our mission of providing access to high quality medicine to the world's seven billion people."

Gilead's executive vice president of Corporate and Medical Affairs, Gregg H. Alton said, "The appointment of Mylan as our branded medicine business partner in India is a result of their strong knowledge of the Indian healthcare system and demonstrated capabilities of supporting and distributing antiretroviral therapies. We have established an excellent working relationship with Mylan over the past few years, and believe that their operations in India will allow the company to best serve the needs of patients in that country."

In addition to distributing branded Gilead medicines, Mylan will manage regulatory and pharmacovigilance activity, such as adverse event reporting, as well as broader medical education initiatives.

Mylan and HIV in India

Mylan has one of the largest field forces exclusively specializing in HIV/AIDS in India. In September 2012, Mylan was selected as a leading supplier of antiretroviral medicine to India's National AIDS Control Organization (NACO). NACO is a division of India's Ministry of Health and Family Welfare and is responsible for overseeing HIV/AIDS control programs in India. India is home to the world's third largest population of people with HIV/AIDS, with approximately 2.4 million people living with the disease.

Gilead Medicines

[Stribild[®]](#) (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is a complete once-daily single tablet regimen for the treatment of HIV-1 infection in adults who are antiretroviral treatment-naive. (U.S. approval, 2012)

[Truvada[®]](#) (emtricitabine/tenofovir disoproxil fumarate) is a fixed-dose once-daily combination pill containing Viread and Emtriva. It is used in combination with other antiretroviral agents for the treatment of HIV infection in adults and pediatric patients 12 years of age and older (U.S. approval, 2004; EU approval, 2005). Once-daily Truvada is also approved for use in combination with safer sex practices, to reduce the risk of sexually acquired HIV-1 infection in adults at high risk. (U.S. approval, 2012)

[Viread[®]](#) (tenofovir disoproxil fumarate) is a once-daily oral nucleotide reverse transcriptase inhibitor (NtRTI) for the treatment of HIV infection in patients 2 years of age and older in combination with other antiretroviral agents. (First U.S. approval, 2001; EU approval, 2002.) Viread is also approved as a treatment for chronic hepatitis B in adults and pediatric patients 12 years of age and older. (U.S. and EU approval, 2008)

Viread® is also indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated and decompensated liver disease and pediatric patients 12 years of age and older. (U.S. and EU approval, 2008)

AmBisome® (amphotericin B liposome for injection) is a treatment for life-threatening, systemic fungal infections in adults. (EU approval, 1990; U.S. approval, 1997). Astellas Pharma US, Inc. commercializes the product in the U.S. and Canada.

This press release includes statements that constitute "forward-looking statements," including with regard to the settlement of the litigation. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: any legal or regulatory challenges to the settlement; strategies by competitors or other third parties to delay or prevent product sales; risks inherent in legal and regulatory processes; and the other risks detailed in the company's periodic filings with the Securities and Exchange Commission. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.

Mylan is a global pharmaceutical company committed to setting new standards in health care. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. mylan.com

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