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Mylan Receives Tentative Approval for "TLE400" Under PEPFAR

- TLE400 is a fixed-combination containing Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 400 mg/300 mg/300 mg -

HERTFORDSHIRE, England and PITTSBURGH, March 20, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL), a leading global pharmaceutical company, today announced receipt of tentative approval from the U.S. Food and Drug Administration under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) for its New Drug Application for Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 400 mg/300 mg/300 mg ("TLE400"). TLE400, an antiretroviral (ARV) fixed-dose combination, will be available in developing countries as a first-line regimen for people being treated for HIV/AIDS.

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Mylan's TLE400 is formulated with a 400 mg dose of Efavirenz, which is less than the standard dose of 600 mg. The Kirby Institute's ENCORE1 trial[1], which used drugs provided by Mylan and Gilead Sciences, showed that a reduced dose of 400 mg Efavirenz is non-inferior to a dose of 600 mg, when combined with Tenofovir and Emtricitabine during 48 weeks in ART-naive adults with HIV-1 infection. TLE400 was recommended by the World Health Organization in 2016 as an alternative for first-line therapy for adults living with HIV.[2]

"Mylan has a strong and sustained commitment to expand access to treatment for HIV/AIDS and other diseases in developing countries. We have nine independent sites engaged in the production and supply of ARV products, ensuring multiple redundancies so we can maintain continuous supply," commented Mylan President Rajiv Malik. "TLE400 is another example of our work to partner with leading global health organizations to innovate and adapt our medicines to meet the unique needs of people living in these settings, in order to accelerate access and to improve treatment outcomes."

There are approximately 37 million people living with HIV/AIDS[3] around the world, with the vast majority living in developing countries. Mylan has invested $250 million in expanding its ARV production capacity, enabling the company to produce 4 billion ARV tablets and capsules every year.

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. 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 market a growing portfolio of approximately 7,500 products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

This press release includes statements that constitute "forward-looking statements," including with regard to the availability of TLE400 in developing countries as a first-line regimen for people being treated for HIV/AIDS; TLE400 being a key addition to Mylan's Infectious Disease franchise and the fight against HIV/AIDS; offering a reduced dosage medicine without compromising efficacy; and Mylan's ability to produce 4 billion ARV tablets and capsules every year. 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 changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

[1] Efficacy of 400 mg efavirenz versus standard 600 mg dose in HIV-infected, antiretroviral-naive adults (ENCORE1): a randomised, double-blind, placebo-controlled, non-inferiority trial; http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62187-X/abstract

[2] WHO, Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection; http://www.who.int/hiv/pub/arv/arv-2016/en/

[3] UNAIDS, AIDS By the Numbers; http://www.unaids.org/sites/default/files/media_asset/AIDS-by-the-numbers-2016_en.pdf

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