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On World AIDS Day, Mylan Announces Plans to be the First to Market Newly-Recommended Antiretroviral Treatment for $99 Per Patient, Per Year

"TLE400," upon regulatory approval by the U.S. FDA, will contain Tenofovir Disoproxyl Fumarate, Lamivudine and a reduced dose of Efavirenz
Newly updated World Health Organization guidelines recommend TLE400 as an alternative first-line regimen for people on AIDS treatment in developing countries

HERTFORDSHIRE, England, BANGALORE, India and PITTSBURGH, Dec. 1, 2015 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that it expects to be the first to launch, upon regulatory approval and for developing country markets funded by international donors, TLE400 (Tenofovir Disoproxyl Fumarate 300 mg + Lamivudine 300 mg + Efavirenz 400 mg) for $99 per patient, per year. Mylan partnered with the Clinton Health Access Initiative (CHAI) to develop TLE400. The significantly reduced price could generate savings of tens of millions of dollars for national AIDS programs that aim to double the 15 million people on antiretroviral (ARV) treatment in developing countries. Mylan expects to file a new drug application (NDA) for TLE400 with the U.S. Food and Drug Administration (FDA) in the first quarter of 2016.

The World Health Organization (WHO) is releasing new ARV guidelines that incorporate, for the first time, TLE400 as an alternative first-line regimen for patients intolerant to the most commonly prescribed combinations today, which use Efavirenz 600 mg. Though there are insufficient data for WHO to recommend TLE400 in persons with tuberculosis co-infection or women who are pregnant, related studies are planned or underway. These studies are being funded by Mylan, in partnership with CHAI, to explore the maximum potential benefits of the product to patients living with HIV.

FDA tentative approval or prequalification by the World Health Organization is a prerequisite for the purchase of ARVs using funds from international donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Mylan expects to be the first company to file TLE400 with FDA and/or WHO and anticipates being the first to market the product for donor-funded procurement in developing countries.

Mylan also is a staunch supporter of revised guidelines from the WHO recommending that anyone who tests positive for HIV be treated with ARVs as soon as possible following diagnosis. In addition, the guidelines recommend that those who are at high risk of being infected also be offered preventive therapy.

Mylan CEO Heather Bresch said, "This World AIDS Day is an opportunity to reflect on the tremendous progress that has been made in the fight against HIV/AIDS, in particular, the 15 million people in developing countries who now have access to ARV treatment. However, today also is a time to recognize that there is much more work to be done to increase access to treatment and to end this epidemic.

Mylan President Rajiv Malik added, "Mylan applauds the new WHO guidelines, as we have long been an advocate for treatment soon after diagnosis to help ensure better health outcomes and reduce transmission. Mylan has a longstanding commitment of bringing to market innovative, high quality, affordable products to help satisfy the unmet needs of HIV/AIDS patients around the world - from our pediatric, heat-stable and combination ARV products, to our recent launch of an at-home HIV test in France, to the expected launch of TLE400 upon approval - and today we reaffirm our unwavering commitment to stemming the tide of HIV/AIDS."

Mylan currently supplies life-saving ARV medicines to nearly 50% of the men, women and children living with the disease and accessing treatment in more than 100 developing countries. Its comprehensive ARV portfolio includes 14 APIs and 50 finished dosage forms in first-line, second-line and pediatric formulations.

About Mylan
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 offer a growing portfolio of more than 1,400 generic and branded pharmaceuticals, including antiretroviral therapies on which nearly 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in approximately 165 countries and territories. Our global R&D and manufacturing platform includes more than 50 facilities, and we are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 30,000-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 Mylan's statements that it expects to be the first to launch TLE400 for $99 per patient, per year; that this significantly reduced price could generate savings of tens of millions of dollars for national AIDS programs that aim to double the 15 million people on ARV treatment in developing countries; that it expects to file an NDA for TLE400 with the FDA in the first quarter of 2016; that though there are insufficient data for WHO to recommend TLE400 in persons with tuberculosis co-infection or women who are pregnant, related studies are planned or underway; about the studies being funded by Mylan in partnership with CHAI to explore the maximum potential benefits of the product to residents living with HIV; that it expects to be the first company to file TLE400 with the FDA and/or WHO and anticipates being the first to market the product for donor-funded procurement in developing countries; and that it is committed to bringing to market innovative, high quality, affordable products to help satisfy the unmet needs of HIV/AIDS patients around the world and to stemming the tide of HIV/AIDS. 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 our inventory of, and our ability to manufacture and distribute, TLE400 and other ARVs; the effect of any changes in our customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on our business; any regulatory, legal, or other impediments to our ability to bring our products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; our ability to protect our intellectual property and preserve intellectual property rights; other uncertainties and matters beyond the control of management; and the other risks detailed in the company's 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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/on-world-aids-day-mylan-announces-plans-to-be-the-first-to-market-newly-recommended-antiretroviral-treatment-for-99-per-patient-per-year-300186205.html

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