Beat: Health

NEWLY-RECOMMENDED ANTIRETROVIRAL TREATMENT FOR $99 PER PATIENT, PER YEAR

MYLAN ANNOUNCES PLANS TO BE THE FIRST

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USPA NEWS - On World AIDS Day, Mylan Announced 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...

On World AIDS Day, Mylan Announced 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.

Mylan announced on December 1, 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 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.

Source : Mylan N.V.

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