

Beat: Health

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

MYLAN ANNOUNCES PLANS TO BE THE FIRST

PARIS - BANGALORE - HERTFORDSHIRE - PITTSBURGH, 03.12.2015, 07:33 Time

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.

Ruby BIRD
<http://www.portfolio.uspa24.com/>
Yasmina BEDDOU

<http://www.yasmina-beddou.uspa24.com/>

Article online:

<https://www.uspa24.com/bericht-6630/newly-recommended-antiretroviral-treatment-for-99-per-patient-per-year.html>

Editorial office and responsibility:

V.i.S.d.P. & Sect. 6 MDSiV (German Interstate Media Services Agreement): Ruby BIRD (Journalist/photographer/Director)

Exemption from liability:

The publisher shall assume no liability for the accuracy or completeness of the published report and is merely providing space for the submission of and access to third-party content. Liability for the content of a report lies solely with the author of such report. Ruby BIRD (Journalist/photographer/Director)

Editorial program service of General News Agency:

United Press Association, Inc.
3651 Lindell Road, Suite D168
Las Vegas, NV 89103, USA
(702) 943.0321 Local
(702) 943.0233 Facsimile
info@unitedpressassociation.org
info@gna24.com
www.gna24.com