A Leader in the Battle Against HIV/AIDS

Mylan continues to be a leader in the battle to eliminate HIV/AIDS by providing access to high quality and affordable antiretrovirals (ARVs) in more than 100 countries. We are currently the largest supplier by volume of ARVs to low- and middle-income countries at costs significantly lower than those charged by brand companies.

This year, we’ve made additional strides in offering important new options for patients. We entered into a partnership to supply rapid diagnostic tests for self-testing in low- and middle-income countries and achieved FDA tentative approval for a once-daily, fixed-dose combination of Dolutegravir, Emtricitabine and Tenofovir Alafenamide in developing countries. In the U.S., the launches of Symfi®, Symfi Lo®, Cimduo® and Efavirenz support our global commitment to expand access to affordable care.

The Mylan team also drives important conversations among healthcare, community and policy experts to encourage innovative solutions for improving the lives of those living with HIV/AIDS and to end the epidemic. For example, last summer Mylan was a major industry sponsor of the world’s largest HIV/AIDS conference in Amsterdam with the International AIDS Society – the first time ever that a generics pharmaceutical company played this role.

Progress Toward Preventing New Infections

Preventing the transmission of HIV is key to ending the epidemic. In addition to supporting multiple prevention awareness campaigns around the world, we manufacture medicines used for pre-exposure prophylaxis (PrEP), for certain countries, taken by HIV-negative people used to reduce the risk of contracting the virus. We are also the supplier in the U.K. for the National Health Service’s PrEP Impact Trial, the largest oral PrEP study to date.

Helping the World’s Smallest Patients

As any caregiver knows, getting babies to take medication can be extremely difficult, especially if it is a bitter-tasting syrup. To help address this issue, Mylan developed a sweet-tasting, pediatric-friendly option for HIV positive infants that can be dissolved in a child’s water or food as part of their HIV regimen. In 2018, we received tentative FDA approval for first-ever Lopinavir/Ritonavir 40mg/10mg oral granules, a pediatric-friendly ARV for HIV-positive infants. We also plan to submit 4 in 1 oral granules to the FDA for approval through the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) program. If approved, this product will be another first of its kind for children living with HIV.

Adding Convenience and Affordability Through Multi-Month Packs

Mylan continues to support the use of multi-month packs for HIV patients. These packs are cheaper on a per-pill basis and more convenient, reducing the need for patients to travel for prescription refills. In its 2018 guidance to countries, PEPFAR identified adoption of multi-month prescriptions as part of the minimum requirement for continued PEPFAR support.

Bringing Diagnostics to Low- and Middle-Income Countries

Making diagnostics more available to patients is essential to moving towards the Joint United Nations Programme on HIV/AIDS (UNAIDS) treatment targets of 90/90/90 (see chart below).

Our agreement with Atomo Diagnostics to commercialize Mylan’s first-ever HIV self-test in low- and middle-income countries is a critical step in helping hard-to-reach populations know their HIV status. The test allows individuals to screen themselves in their own homes with a single drop of blood obtained from a fingertip.

Mylan Supports the UNAIDS Targets for HIV:²

- By 2020, 90% of all people living with HIV will know their HIV status
- By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy
- By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression

Focusing on Awareness, Prevention and Treatment for Hepatitis

One of the major barriers to effectively treating hepatitis B and C around the world is that many patients are unaware they have the disease due to limited education about the condition and lack of access to quality screenings. To help combat this problem, Mylan launched multiple campaigns in some of the hardest-hit countries, including India, Egypt, Thailand and the Philippines. In addition to offering free screenings and consultations, the campaigns promote the importance of screening, disease management, treatment options and the steps needed to increase a patient’s adherence to treatment. Mylan has also developed new partnerships such as those with the governments of Burkina Faso, Ivory Coast and Cameroon to launch hepatitis B and C programs which bundle treatment and diagnostics, facilitate screening programs and build patient and provider awareness.

Moving forward, we hope to significantly increase the number of patients reached by Mylan’s products by participating in expanded government programs. We will also continue working with multilateral agencies such as the United Nations Development Programme and UNAIDS. To further support access to hepatitis C (HCV) treatment, Mylan has applied for WHO prequalification for a number of HCV direct acting antivirals and is awaiting approval.

Partnering to Treat Tuberculosis

In September 2018, the U.N. held the first-ever High-Level Meeting for Tuberculosis. This established tuberculosis as a global priority, garnering commitments from all over the world to scale-up programs to fight tuberculosis (TB), which kills more people annually than AIDS.

Drug resistance poses a serious challenge to treating TB. South Africa and India are considered by the World Health Organization (WHO) as among the highest-burden countries for multi-drug resistant tuberculosis (MDR-TB) and TB/HIV co-infection, with more than 150,000 estimated new cases of MDR-TB/rifampicin-resistant TB in 2015 alone.¹

To provide more MDR-TB patients with access to treatment, Mylan has been granted an exclusive license from Otsuka Pharmaceuticals to prioritize access to Deltyba® in South Africa and India. We further agreed to extend exclusive commercial rights and registration responsibilities to many other high MDR-TB burden countries. Looking forward, Mylan is assessing ways to reduce the cost of treatment to make it more accessible. We are also exploring additional partnerships to further support the development and delivery of better, faster-acting and affordable TB treatments.