

# HIV Treatment Expansion



Gilead Sciences has contributed significantly to the improvement and simplification of antiretroviral HIV therapy and to expanding access to therapy for appropriate patients living in developing countries.

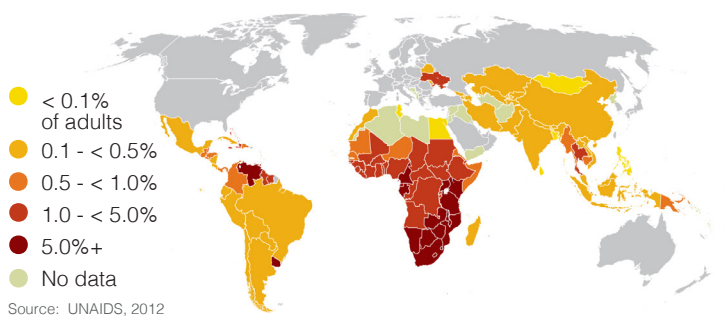
## Snapshot

- **7 million people** with HIV in low- and middle-income countries are receiving a Gilead-based HIV regimen\*
- The lowest price of generic tenofovir disoproxil fumarate (TDF)<sup>1</sup> is currently **US \$4.00** per patient per month
- Gilead was the **first company to license HIV drugs** to the Medicines Patent Pool

## HIV in the Developing World

More than 35 million people are living with HIV-1, the vast majority of them in the developing world. More than two million people are newly infected with HIV every year.<sup>2</sup> Over the past decade, the international community has made enormous progress in expanding access to antiretroviral treatment: between 2002 and 2013, the number of people in low- and middle-income countries receiving antiretroviral therapy increased from 300,000 to 11.7 million.<sup>3,4</sup> Since 1995, HIV therapy has averted 7.6 million AIDS-related deaths worldwide.<sup>5</sup> Additionally, there is growing evidence suggesting that people receiving HIV therapy are less likely to transmit HIV to other people, meaning that antiretroviral treatment may have an important role in HIV prevention.<sup>6</sup>

### HIV Prevalence in the Developing World



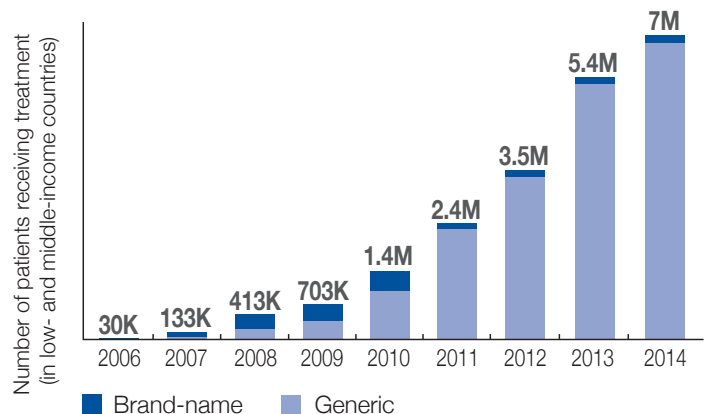
Yet substantial needs remain, with treatment scale-up a top priority. Of the 35 million people with HIV worldwide, more than 28 million should be receiving antiretroviral therapy according to 2013 World Health Organization (WHO) guidelines recommending earlier treatment initiation, leaving nearly 16 million people still in need of treatment.<sup>7</sup>

## Gilead's Approach

Recognizing that the greatest need for HIV treatment is in the least-developed parts of the world, the company has put in place innovative programs and partnerships to expand global access to its medicines.

**Tiered Pricing.** A key principle of Gilead's HIV treatment access efforts has been tiered pricing of its branded antiretroviral medicines. Developing countries are divided into two pricing tiers – low-income and lower middle-income – based on national income and HIV prevalence. Viread<sup>®</sup> (or TDF) has been available at reduced prices in developing countries since 2003, and Truvada<sup>®</sup> (emtricitabine co-formulated with TDF) and single tablet regimen Stribild<sup>®</sup> (elvitegravir / cobicistat / emtricitabine / TDF)<sup>8</sup> were each added to the Access program following their U.S. approvals in 2004 and 2012, respectively. WHO recommends TDF-based regimens among the preferred options for initiating HIV treatment.<sup>9</sup>

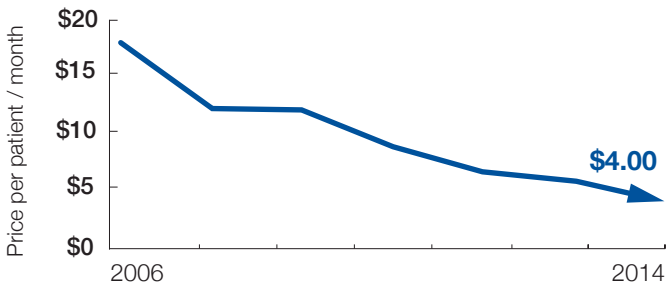
### Access to Gilead HIV Medicines



\*TDF-containing regimens from tech transfer recipients, branded sales, direct and MPP licensees

**Generic Licensing Partners.** In 2006 Gilead began entering into voluntary licensing agreements with Indian manufacturers, granting them rights to produce and sell high-quality, low-cost generic versions of Gilead medicines.

### Lowest TDF Price



Generic licensee selling prices (USD)

In 2011, Gilead became the first innovator pharmaceutical company to sign an agreement with the Medicines Patent Pool (MPP), an international organization that expands access to HIV medicines through the sharing of drug patents. As a result, MPP is authorized to sub-license generic drug manufacturers to produce Gilead medicines for developing countries.

Currently, 17 Indian manufacturers, one South African and one Chinese company hold licenses to produce Gilead HIV medicines. Over the past eight years, licensing partners have lowered the developing world prices of Viread and Truvada by 80 percent. The lowest price of generic Viread is currently US \$4.00 per patient per month.

## Working Locally to Advance Access

Lowering prices is just one part of successfully scaling up HIV treatment. Also critical are in-country activities that support drug availability and use, including product registration, medical and clinical education, demand forecasting and collaborative research.



October 2013 medical education event in Myanmar supported by Gilead

Gilead conducts many of these activities in partnership with regional business partners that distribute its medicines throughout Africa, Asia, the Caribbean, Eastern Europe, Latin America, the Middle East and the Pacific region. In addition to delivering treatment, these partners help register medicines with regulatory authorities, ensuring that dossiers conform to national requirements and are processed efficiently, and assist with education for healthcare workers.

## Country Program Examples

**Myanmar:** Gilead donates generic Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate)<sup>10</sup> to the Myanmar government's National AIDS Program to treat patients at public hospitals.

- The donation supports the HIV treatment of 2,000 people in Myanmar who are living with HIV.
- Gilead also provides educational materials and financial support to strengthen local and regional health systems.

**Tanzania:** Gilead partners with the Good Samaritan Foundation of the Roman Catholic Church to support an HIV “test-and-treat” demonstration project in Shinyanga, a province in northern Tanzania. It is designed to save lives and boost HIV prevention efforts in the region.

- The program will screen 120,000 patients at four health centers in Shinyanga for HIV and provide ARVs to 20,000 diagnosed individuals.

**Ethiopia and Uganda:** Gilead supported the Mayo Clinic and Chelsea Westminster Hospital's pilot HiV-Link program, which leverages mobile phone technology to connect healthcare providers in rural Ethiopia and Uganda with HIV treatment experts in the United States and United Kingdom. Through HiV-Link, African healthcare workers can text specific clinical questions to U.S./U.K.-based physicians and receive rapid responses that help to guide their treatment decisions for patients.

### References

- <sup>1</sup> Prescribing Information, Oct 2013. Available at: [http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/viread/viread\\_pi.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/viread/viread_pi.pdf)
- <sup>2</sup> UNAIDS. The Gap Report. (2014).
- <sup>3</sup> WHO. HIV/AIDS Fact Sheet (July 2014).
- <sup>4</sup> WHO. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection (2013).
- <sup>5</sup> UNAIDS. The Gap Report (2014).
- <sup>6</sup> Cohen, M., et al. Prevention of HIV-1 infection with early antiretroviral therapy. *New England Journal of Medicine*, 2011;365:493-505.
- <sup>7</sup> UNAIDS. UNAIDS Report on the Global AIDS Epidemic (2013).
- <sup>8</sup> Prescribing Information, Oct 2013. Available at: [http://www.gilead.com/~media/Files/pdfs/medicines/hiv/stribild/stribild\\_pi.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/hiv/stribild/stribild_pi.pdf)
- <sup>9</sup> WHO. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection (2013).
- <sup>10</sup> Prescribing Information, Oct 2013. Available at: [http://www.gilead.com/~media/Files/pdfs/medicines/hiv/atrilpa/atrilpa\\_pi.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/hiv/atrilpa/atrilpa_pi.pdf)