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New high-quality antiretroviral therapy to be launched in South Africa, Kenya and over 90 low- and middle-income countries at reduced price
Negotiated pricing agreements have lowered costs and will improve access to quality treatment for people living with HIV

New York – A breakthrough pricing agreement has been announced which will accelerate the availability of the first affordable, generic, single-pill HIV treatment regimen containing dolutegravir (DTG) to public sector purchasers in low- and middle-income countries (LMICs) at around US\$75 per person, per year. The agreement is expected to accelerate treatment rollout as part of global efforts to reach all 36.7 million people living with HIV with high-quality antiretroviral therapy. UNAIDS estimates that in 2016, just over half (19.5 million) of all people living with HIV had access to the lifesaving medicines.

DTG, a best-in-class integrase inhibitor, is widely used in high-income countries and is recommended by the World Health Organization (WHO) as an alternative first-line HIV regimen, as well as a preferred treatment by the U.S. Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents, among many others. In addition to improving treatment quality and retention, widespread use of DTG is expected to lower the cost of first-line HIV treatment regimens while also reducing the need for more expensive second- and third-line regimens. In July 2017, WHO issued guidance to countries on how to safely and rapidly transition to DTG-based antiretroviral treatment.

This agreement, announced by the governments of South Africa and Kenya, together with the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Clinton Health Access Initiative (CHAI), the Bill & Melinda Gates Foundation (BMGF), Unitaid, the United Kingdom's Department for International Development (DFID), the United States President's Emergency Plan for AIDS Relief (PEPFAR), the U.S. Agency for International Development (USAID), and the Global Fund to Fight AIDS, Tuberculosis and Malaria, with Mylan Laboratories Limited and Aurobindo Pharma, takes an important step toward ensuring the availability of worldwide high-quality treatment for HIV.



“This agreement will improve the quality of life for millions of people living with HIV,” said UNAIDS Executive Director Michel Sidibé. “To achieve the 90-90-90 treatment targets, newer, affordable and effective treatment options must be made available—from Baltimore to Bamako—without any delay.”

WHO Director-General, Dr. Tedros Adhanom stated, “WHO welcomes this agreement which will make it possible to reach millions of people with better, more affordable and durable HIV drugs. This will save lives for the most vulnerable, bringing the world closer to the elimination of HIV. We congratulate South Africa, Kenya, CHAI and others on this landmark agreement. WHO will support countries in the safe introduction and a swift transition to this game-changing new treatment.”

This one pill, once-a-day generic fixed-dose combination of tenofovir disoproxil fumarate, lamivudine, and dolutegravir (TLD) was developed by Mylan and Aurobindo under licensing agreements from ViiV Healthcare, the original developer of DTG. Mylan and Aurobindo both recently received tentative approval from the U.S. Food and Drug Administration (FDA) for their products under the United States PEPFAR program. Clinical studies demonstrated that treatment regimens that use DTG result in more rapid suppression of viral load, fewer side effects, and greater potency against drug resistance than current regimens used in LMICs.

“I am excited about this innovative agreement which will allow the government of South Africa to accelerate the introduction of the dolutegravir-based fixed-dose combination which will greatly benefit our patients due to its superior therapeutic qualities,” said Minister of Health of South Africa Dr. Aaron Motsoaledi. “The considerable price reductions could yield savings of up to US\$900 million over the next six years for us, which means that we can initiate additional patients on treatment with the same amount of resources. Ramping up treatment with good viral suppression will enable us to reach HIV epidemic control more quickly. We are aiming at launching the new tender in April 2018.”

“In the antiretroviral therapy guidelines launched in July 2016, the Ministry of Health made provisions for use of newer antiretroviral medicines such as dolutegravir,” said Dr. Cleopa Mailu, Cabinet Secretary of Health in Kenya. “Research has shown that dolutegravir offers better tolerability, fewer adverse drug reactions, fewer drug interactions, and higher genetic barrier to resistance. It is with this in mind that, in July this year, Kenya approved its inclusion in the National ART Program.”

“The Global Fund is excited to be part of this great initiative that will help us save more lives,” said Marijke Wijnroks, Interim Executive Director of the Global Fund. “As we strive to end HIV as an epidemic, we are committed to supporting people affected by diseases to access better products.”

The BMGF, with the support of CHAI, recently completed ceiling price agreements with Mylan and Aurobindo with the goal of accelerating the availability of the new fixed-dose combination to the public sector in over 90 LMICs at reduced pricing. The agreements, which set an upper price limit for TLD, are by some estimates expected to save public sector purchasers over US\$1 billion over the next six years.

“As a doctor with deep, personal experience of the heartache and despair caused by HIV and AIDS, I’m excited by the prospect of bringing better treatment to more people than ever before,” stated BMGF CEO Sue Desmond-Hellmann. “This unprecedented new partnership - the largest of its kind ever seen in



global health - will transform millions of lives by making a highly-effective drug more affordable to countries with the largest numbers of people living with HIV. The Bill & Melinda Gates Foundation is uniquely placed to help in this endeavor - and I'm delighted that our investment will give millions more people a shot at leading a healthy, productive life."

Ministries of Health and program managers should anticipate being able to order TLD in 2018 at around a projected average price of US\$75 per patient, per year. Further pricing details are available upon request to Mylan or Aurobindo. The ceiling price agreements apply to purchases for public sector use in all 92 countries covered under ViiV Healthcare's dolutegravir licensing agreement, representing over 90 percent of people in LMICs currently living with HIV.

To build momentum for TLD and familiarize healthcare workers with the drug in resource-limited settings, Unitaid partnered with CHAI beginning in late 2016 to make generic DTG single tablets available in three early adopter countries: Kenya, Nigeria, and Uganda. Partnering with WHO, USAID, and the Ministries of Health, this innovative initiative is giving countries an opportunity to improve treatment offerings for their patients while also generating critical evidence on the use of DTG in certain populations, including pregnant women and tuberculosis (TB) co-infected patients.

"Unitaid's investments have laid the foundation for the ground-breaking introduction of TLD at an affordable price," said Lelio Marmora, Unitaid's Executive Director. "Through our catalytic work we are overcoming barriers, thereby enabling countries like Kenya to access the latest HIV treatments on the market."

"This groundbreaking agreement will help improve the lives of millions of patients by reducing costs and increasing availability of a one pill, once daily fixed-dose-combination including dolutegravir," stated Ira Magaziner, CEO of CHAI. "This drug combination is better tolerated and more effective and will lead to improved health outcomes by ensuring that fewer HIV patients develop drug resistance and that more remain on treatment."

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About UNAIDS

The Joint United Nations Programme on HIV/AIDS (UNAIDS) leads and inspires the world to achieve its shared vision of zero new HIV infections, zero discrimination and zero AIDS-related deaths. UNAIDS unites the efforts of 11 UN organizations—UNHCR, UNICEF, WFP, UNDP, UNFPA, UNODC, UN Women, ILO, UNESCO, WHO and the World Bank—and works closely with global and national partners towards ending the AIDS epidemic by 2030 as part of the Sustainable Development Goals. Learn more at unaids.org and connect with us on [Facebook](#), [Twitter](#), [Instagram](#) and [YouTube](#).



About the Clinton Health Access Initiative

Founded in 2002, by President William J. Clinton and Ira C. Magaziner, the Clinton Health Access Initiative, Inc. (“CHAI”) is a global health organization committed to saving lives, reducing the burden of disease and strengthening integrated health systems in the developing world. Learn more at www.clintonhealthaccess.org

About the Bill & Melinda Gates Foundation

Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. In developing countries, it focuses on improving people's health and giving them the chance to lift themselves out of hunger and extreme poverty. In the United States, it seeks to ensure that all people—especially those with the fewest resources—have access to the opportunities they need to succeed in school and life. Based in Seattle, Washington, the foundation is led by CEO Sue Desmond-Hellmann and Co-chair William H. Gates Sr., under the direction of Bill and Melinda Gates and Warren Buffett.

About Unitaid

Unitaid invests in new ways to prevent, diagnose and treat HIV/AIDS, hepatitis C, tuberculosis and malaria more quickly, affordably and effectively. It brings the power of new medical discoveries to the people who most need them. And it helps set the stage for the large-scale introduction of new health products by collaborating with Governments and funding partners such as PEPFAR and the Global Fund.

About the Global Fund

The Global Fund is a 21st-century partnership designed to accelerate the end of AIDS, tuberculosis and malaria as epidemics. As a partnership between governments, civil society, the private sector and people affected by the diseases, the Global Fund mobilizes and invests nearly US\$4 billion a year to support programs run by local experts in more than 100 countries. The Global Fund's operating costs are approximately 2 percent of grants under management, reflecting an exceptionally high degree of efficiency. By challenging barriers and embracing innovative approaches, we are working together to better serve people affected by the diseases.