



PRESS RELEASE

Three new agreements announced with the potential to expand access to innovative HIV treatment in low- and middle-income countries

HARARE/GENEVA, 30 November 2015—The Clinton Health Access Initiative, Inc. (CHAI), UNAIDS, and UNITAID announce today three new agreements that could increase access to more sustainable HIV drug regimens at reduced prices, pending stringent regulatory approval and/or World Health Organization (WHO) pre-qualification.

These agreements have the potential to increase access to state-of-the-art HIV treatment regimens for people living with HIV in low- and middle- income countries. The regimens are expected to be more durable and produce fewer side effects than existing drugs and are included in the revised 2015 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.

"Ensuring access to the most innovative and effective medicines for all people with HIV is essential in every country," said Dr Margaret Chan, WHO Director-General. "I applaud CHAI and all the partners involved for these agreements, which move us one step closer to a world without AIDS."

Under the first agreement, Aurobindo Pharma Limited has agreed to make generic dolutegravir (DTG) available for US\$44 per patient per year, subject to regulatory approval. At this price, a DTG-containing regimen is comparable in price to the leading first-line regimen containing efavirenz (EFV). WHO now recommends DTG as an alternate first-line therapy in those intolerant of efavirenz. There are, as yet, insufficient data to recommend the use of DTG in women who are or wish to become pregnant or for people on treatment for tuberculosis; associated studies are currently underway.

The launch price agreement for DTG was made possible in part by the leadership of the Government of Kenya, which agreed to incorporate DTG into national treatment guidelines and begin providing DTG to suitable patients as soon as regulatory approval is received.

ViiV Healthcare licensed Aurobindo for generic DTG, enabling Aurobindo to file for tentative approval with the U.S. Food and Drug Administration (US FDA) for the single formulation in May 2015, making this the fastest filing for a generic antiretroviral following approval for the originator, which occurred in August 2013. As a part of today's agreement, Aurobindo confirmed they will also file for a one-pill, once per day fixed-dose combination of DTG (combined with tenofovir disoproxil fumarate and lamivudine) with the US FDA by Q3 2016. ViiV has also enabled other manufacturers to develop this fixed-dose combination through an earlier license provided to the Medicines Patent Pool.

"Bringing effective new HIV drugs to the millions of people who have still not initiated treatment is a big challenge in global health today," said UNITAID Executive Director Lelio Marmora. "The

agreements announced between CHAI, UNAIDS and UNITAID with four manufacturing partners will be crucial to having game-changing medications included in WHO and national guidelines and brought to market more speedily."

Secondly, Mylan Laboratories Limited will file for US FDA tentative approval for an alternate first-line fixed-dose combination regimen in Q1 2016, and make it available for US\$99 per patient per year, subject to regulatory approval. The new product, TLE400, contains tenofovir disoproxil fumarate, lamivudine, and a reduced dose of efavirenz, and produced positive results in the ENCORE1 clinical study by the Kirby Institute at the University of New South Wales, Australia. Again, there are insufficient data to recommend this combination in TB patients or women who are pregnant, but related studies are either planned or underway. The new price marks an 8% decrease from current prices and could generate US\$80-100 million in savings globally through 2020, if approved. To foster future competition and ensure supply security, the Kirby Institute and CHAI have agreed to make the study data available to companies seeking to develop other generic versions of TLE400.

"Ensuring access to high quality and affordable HIV drugs for all people living with the virus is a top priority for Zimbabwe," said Honorable Dr. David Parirenyatwa, Minister of Health and Child Care in Zimbabwe. "We look forward to adopting TLE400 as our standard first-line treatment as soon as ongoing efficacy trials amongst pregnant women and TB patients are complete and it receives the appropriate regulatory approvals and is available. The clinical benefits and affordability make it the right choice for Zimbabwe, and we thank CHAI, UNAIDS, UNITAID and Mylan for helping to make this possible."

Thirdly, a new partnership between Janssen: Pharmaceutical Companies of Johnson & Johnson and CHAI will facilitate the development and delivery of a heat-stable formulation of darunavir/ritonavir (DRV/r) to enhance its availability in resource-limited settings. For the first time, the revised 2015 WHO HIV treatment guidelines include DRV/r as an alternative component of second- or third-line HIV treatment regimens for adolescents and adults. DRV/r has a favorable resistance and tolerability profile compared to the current treatment options (lopinavir/ritonavir and atazanavir/ritonavir) and represents a once-daily regimen option for patients on second-line treatment. CHAI is also partnering with Hetero Drugs Limited to accelerate development of a generic version of DRV/r, and Hetero has committed to file for regulatory approval by Q3 2016. Together, these partnerships will aim to address development, manufacturing, and uptake barriers in order to expedite DRV/r availability in resource-limited settings. Janssen is the originator manufacturer for DRV; please see accompanying full Product Information for more details.

"As a global community, we need to ensure that the 15.8 million people currently on HIV treatment, and the millions more to be initiated on treatment over the next few years, have access to the best possible drugs to treat the disease and prevent further spread of the disease," said Ira Magaziner, CEO of CHAI. "The agreements announced today are a great step forward in that effort, and CHAI is pleased that our continued collaboration with UNAIDS, UNITAID, WHO, the British Government, and industry partners has enabled this success."

Together, these agreements have the potential to enhance access to optimal HIV treatment regimens and improve treatment outcomes for people in low-and middle-income countries. Increased access to treatment, retention in care, and improved treatment outcomes are critical to reaching the ambitious global 90-90-90 treatment targets, which aim to lay the foundation to

end AIDS as a public health threat by 2030. The 90-90-90 targets require that by 2020, 90 percent of all people living with HIV will know their HIV status; 90 percent of all people with an HIV diagnosis will receive sustained antiretroviral therapy; and 90 percent of all people receiving antiretroviral therapy will achieve viral suppression.

“Access to life-changing HIV treatment should not be a lottery based on where you happen to live. To ensure equity and sustainability in the global AIDS response, continued collaboration with our industry and technical partners is essential to make optimal first-, second- and third-line HIV treatment regimens available and affordable for all people living with HIV,” said Michel Sidibé, UNAIDS Executive Director. “We welcome today’s agreements which we hope will improve treatment options available to all countries and help us to achieve our ambitious 90-90-90 treatment targets.”

CHAI and UNITAID are committed to an open, competitive marketplace for the products included in these agreements, and the suppliers included here are those that are closest to having product dossiers ready for stringent regulatory approval and/or WHO pre-qualification; any suppliers who are committed to developing these products to the same standards will also receive support.

CHAI’s contribution was made possible through the generous support of UNITAID and the UK Department for International Development.

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Contact

For all press inquiries, please email press@clintonhealthaccess.org

Clinton Health Access Initiative, Inc.

The Clinton Health Access Initiative, Inc. (CHAI) is a global health organization committed to strengthening integrated health systems and expanding access to care and treatment in the developing world. CHAI’s solution-oriented approach focuses on improving market dynamics for medicines and diagnostics; lowering prices for treatment; accelerating access to life-saving technologies; and helping governments build the capacity required for high-quality care and treatment programs. For more information, please visit clintonhealthaccess.org and connect with us on Facebook and Twitter.

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 and Twitter.

UNITAID

UNITAID is an international organization founded in 2006 that finds new ways with partners to prevent, treat and diagnose HIV/AIDS, tuberculosis and malaria more quickly, more cheaply and more effectively. Its investments help turn groundbreaking ideas into effective solutions that enable partners to achieve the highest impact for those in need. Learn more at www.unitaid.org