Child-friendly formulation of WHO-recommended HIV treatment approved by FDA

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The Paediatric HIV Treatment Initiative welcomes this important step towards closing the treatment gap for children with HIV

Infants and young children living with HIV will finally have access to an improved formulation of an antiretroviral (ARV) treatment, following the U.S. Food and Drug Administration's (FDA) tentative approval last week of lopinavir/ritonavir (LPV/r) oral pellets developed by the Indian generic company Cipla.

"The announcement of tentative FDA approval of the lopinavir/ritonavir oral pellet formulation is an important step forward in increasing access to World Health Organization-recommended antiretroviral treatment for children under three years of age," said Ambassador Deborah L. Birx, M.D., U.S. Global AIDS Coordinator and U.S. Special Representative for Global Health Diplomacy. "This supports the goals of key PEPFAR initiatives to improve paediatric HIV/AIDS services, including the Accelerating Children's HIV/AIDS Treatment Initiative and the Global Pediatric ARV Commitment to Action".

Until now, the only available version of this combination treatment was a harsh-tasting syrup that required refrigeration and contained 40% alcohol. Only a quarter of children with HIV are currently on treatment and the lack of child-adapted formulations contributes to this unacceptable situation.

"UNITAID and its partners in the Paediatric HIV Treatment Initiative (PHTI) also welcome the approval of these oral pellets, which brings us a step nearer to closing the shameful treatment gap for the 3.2 million children living with HIV around the world," said Lelio Marmora, Executive Director of UNITAID which is funding the development of paediatric formulations for HIV.

Importantly, intellectual property issues around access to future LPV/r combinations will be reduced, thanks to a licensing agreement the Medicine Patent Pool (MPP) signed in in December 2014 with AbbVie, the patent holder for LPV/r. "This is a crucial licence for paediatric programmes as it benefits low- and middle-income countries where 99% of children with HIV in the developing world live," said Greg Perry, Executive Director of the MPP.

As part of its programme to develop improved HIV medicines for children, the Drugs for Neglected Diseases initiative (DNDi) is working with Cipla to ensure the new pellets are registered and adopted through a large "implementation study" that will be carried out in several sub-Saharan African countries. In 2013, UNITAID gave an important grant to DNDi for its work in this area.

"Within a few weeks, the first batches of the new pellets will be shipped to Kenya, and DNDi and our partners on the ground will quickly introduce them along with other needed ARVs so that children can benefit immediately," said Dr Marc Lallemant, Head of DNDi's Paediatric HIV Programme.

Last week's FDA approval is an important step towards developing what children with HIV really need to live healthily. Supported by UNITAID, DNDi and Cipla aim as the next stage to develop two "4-in-1" fixed-dose combinations of LPV/r with other key ARVs (zidovudine/lamivudine and abacavir/lamivudine) that are recommended by the World Health

Organization (WHO). Taste-masked versions of these combinations will be even easier to take than the new pellets and should enable large-scale expansion of access to treatment for infants and young children with HIV.

"In 2006 only 70,000 children were receiving HIV treatment, but with the partnership of UNITAID we've been able to work hand in hand with national governments to put more than 760,000 children on antiretroviral therapy," said Dr Nandita Sugandhi, Senior Clinical Officer at the Clinton Health Access Initiative (CHAI). "But there remain thousands of children who are still not accessing treatment and our efforts must continue to ensure that children living with HIV are not left behind."

More information: www.accessdata.fda.gov/drugsat … 25Orig1s000TAltr.pdf

Provided by Drugs for Neglected Diseases Initiative

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