Study begins in Kenya for recently-approved pediatric HIV treatment

December 1 2015

The Drugs for Neglected Diseases initiative (DNDi) has begun an implementation study of a recently-approved paediatric antiretroviral (ARV) treatment in order to address the urgent need for better medicines for children living with HIV. This study, which has begun in Kenya, is an important step towards DNDi's ultimate goal of developing, together with the Indian generic pharmaceutical company Cipla Ltd and in partnership with UNITAID, improved and easy-to-take combinations of the key HIV medicines children need to survive into adulthood.

In June 2015, the U.S. Food and Drug Administration (FDA) approved lopinavir/ritonavir (LPV/r) oral pellets developed by Cipla. The World Health Organization (WHO) recommends LPV/r-based combination treatments for children under three years old, but access to this combination has been limited. Until now, the only available version of LPV/r was a bad-tasting syrup that requires refrigeration and contains 40% alcohol. Cipla's new LPV/r pellets are an important improvement - they do not require refrigeration, do not contain alcohol, and can be easily given by mixing with food or with breastfeeding. Initially tested in Uganda, in a key study led by the UK's Medical Research Council's clinical trial unit, the pellets represent an important step away from the alcohol-laden liquid formulation.

DNDi's new implementation study, called the LIVING study, will introduce these pellets in the field (in combination with a dispersible tablet containing two additional ARVs), to assess their effectiveness, safety, ease-of-use, and acceptability. LIVING is a Phase IIIb, open-

label, non-randomized single arm study and will be limited to children living with HIV who are not able to swallow tablets.

'One of the reasons such a large number of children with HIV are not on treatment is that paediatric ARV formulations are not adapted to tropical environments and are very hard for them to take', said Dr Marc Lallemant, Head of DNDi's Paediatric HIV Programme.'With 2.6 million children with HIV, we need to get the best treatments and formulations to them as soon as they become available.'

Looking further ahead, the main goal of DNDi's paediatric HIV programme is the development of two improved child-friendly fixed-dose combinations that contain four key ARVs (LPV/r+lamivudine+zidovudine or abacavir). Called '4-in-1', these combinations will have good taste and be even easier to take than the LPV/r pellets. Cipla is currently developing these new formulations and identified three potential taste-masked formulations to take forward.

'We need better formulations of these life-saving treatments but we also need improved testing for babies born to mothers with HIV', said Dr Dalton Wamalwa, Associate Professor, Department of Paediatrics and Child Health, University of Nairobi and Coordinating Principal Investigator of the LIVING Study. 'If, with improved testing, we could get babies on treatment early, we could save thousands of lives.' Without treatment, 50% of children infected with HIV die before their second birthday and 80% die before their fifth birthday.

Patients have already been enrolled in the LIVING study at three sites in Kenya: Kenyatta National Hospital, Gertrude's Children Hospital, and FACES Kisumu. The study will soon be expanding to more sites in Kenya and then other sub-Saharan countries at the heart of the HIV/AIDS epidemic, including Uganda, Tanzania, South Africa, and Zimbabwe. Children involved in the LIVING study will be switched to

the improved 4-in-1 formulations as soon as they are available.

DNDi's paediatric HIV programme is made possible with support from UNITAID, the French Development Agency (AFD), Médecins Sans Frontières (MSF), and the UBS Optimus Foundation.

DNDi has also launched a Paediatric HIV Toolkit for community healthcare workers, activists, and caregivers and has provided a current update of the paediatric HIV programme.

Provided by Drugs for Neglected Diseases Initiative