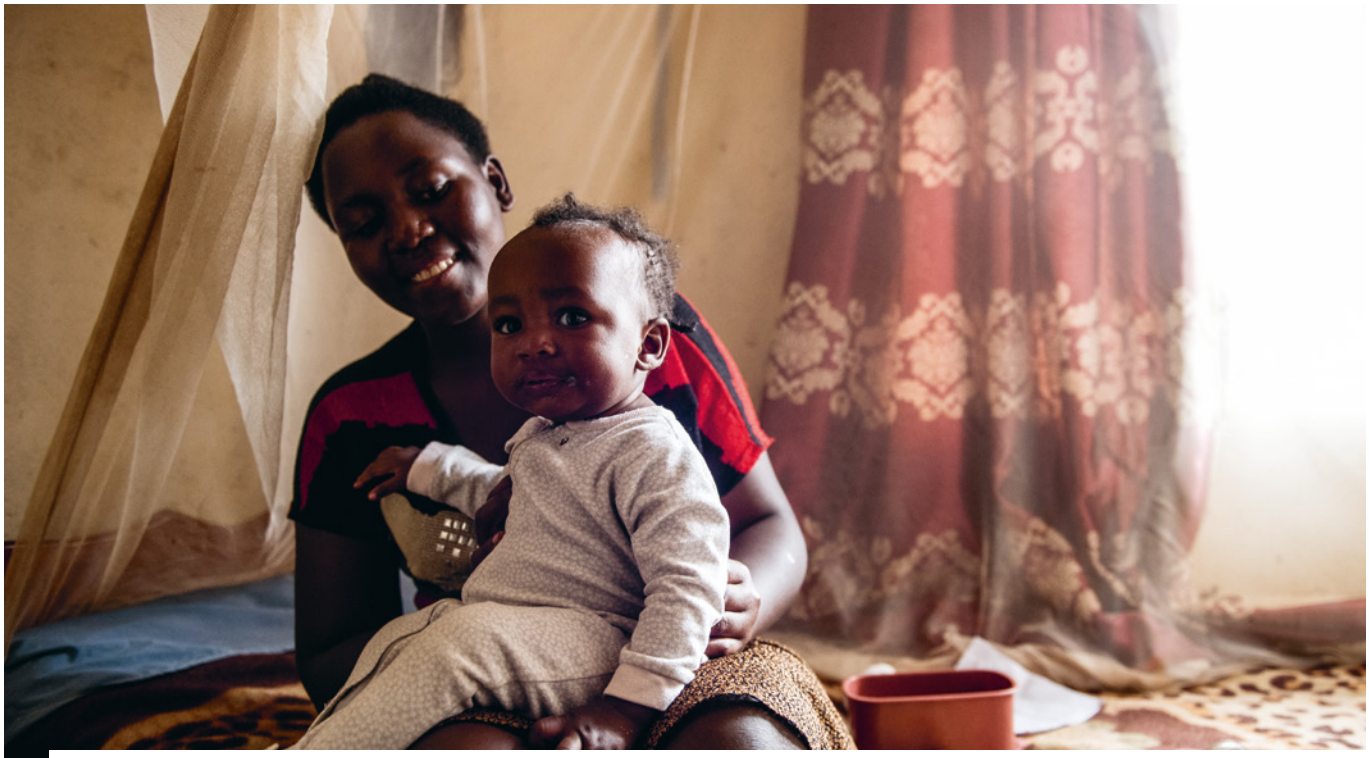

> **At the moment my daughter is doing well, the capsules are working good and are easy to use after the nurse showed me how to use them.**

Jacklyne Kabakama *23, with her daughter in Kihara village, a rural area near Fort Portal, Uganda , speaking of the 2-in-1 oral pellet formulation.*

PAEDIATRIC HIV

ENDING THE NEGLECT OF BABIES & YOUNG CHILDREN

The needs of children living with HIV are neglected by pharmaceutical companies. Because the market for paediatric HIV medicines is small, they have never been a priority for commercial drug development. Treatment coverage among children living with HIV is unacceptably low, with only 52% of HIV-positive children receiving treatment in 2017. Half of these children continue to receive suboptimal regimens, putting them at risk of resistance and treatment failure.

1.8 MILLION children living with HIV, 90% in sub-Saharan Africa

180,000 new infections among children every year

ONLY **52%** of children living with HIV were receiving antiretroviral therapy in 2017

THE TREATMENT CHALLENGE

Very young children cannot swallow tablets intended for adults. Until recently, the only paediatric formulation for one of the main antiretrovirals (ARVs) to treat HIV was a foul-tasting syrup that not only contains 40% alcohol but must also be refrigerated – a challenge for the many living without electricity. Caregivers struggle to get infants and young children to take the syrup, as they are likely to spit it out or refuse it entirely. Children also require special dosing because when they do not get the proper dosage of an ARV, they can develop resistance to a drug, which has serious consequences for their health and future treatment options.

DND*i* aims to help end the neglect of paediatric HIV by developing optimal child-friendly antiretroviral formulations for children living with HIV, with a special focus on infants and young children who are at the highest risk of dying without treatment.

Scaling up with the right tools now: the LIVING study

The initial priority of DND*i*'s paediatric HIV programme was to introduce optimal formulations for children as soon as possible. To do this, DND*i* has been running a study with over 1,000 children in Kenya, Uganda, and Tanzania – one of the biggest paediatric HIV cohorts in the world – to help increase uptake of a '2-in-1' oral pellet formulation. The 2-in-1, developed by Cipla, combines two recommended ARVs (lopinavir and ritonavir) and can replace foul-tasting syrups that require refrigeration and older paediatric ARVs that are no longer recommended.

In February 2018, interim results of the study were released, showing that 83% of the children in the study had successfully suppressed HIV levels after 48 weeks of treatment with the 2-in-1 oral pellets, compared to just 55% at the beginning of the study. These results show that the 2-in-1 is effective and well-tolerated by children.

Progress towards a 4-in-1 combination

The LIVING study is providing key data on optimized treatment regimens for young children. Nevertheless, the pellets still have a bitter taste and need to be taken with separate abacavir and lamivudine tablets – which complicates the job of caregivers. Hope for optimal treatment lies in a new 4-in-1, which will contain all four recommended drugs in a single formulation, and be better taste-masked for kids.

DND*i* is getting closer to its goal of helping deliver a 4-in-1 treatment that is easy to use, safe, effective, palatable, and does not require refrigeration. Cipla, DND*i*'s partner, is planning to submit an application for regulatory approval in late 2019. DND*i* will soon start the LOLIPOP study of the 4-in-1 in Uganda to provide clinical data on infants and young children, and produce the necessary evidence for worldwide scale-up.

Along with the paediatric formulations of new-generation antiretrovirals being developed by others, the 4-in-1 will be an important tool in closing the substantial treatment gap between adults and young children in coming years.