



FACTS



50%

of children living with HIV will die before their second birthday without treatment



Only

54%

of children are receiving life-saving treatment



180,000

people die every year from HIV-related cryptococcal meningitis

HIV

Ensuring access to life-saving treatment for children and people with advanced HIV

The antiretroviral treatment revolution has enabled millions of people with HIV to live long and healthy lives. But a lack of appropriate treatments for children and people with advanced HIV continues to leave many behind – almost half of the nearly 2 million children living with the disease are not accessing treatment. And hundreds of thousands of people still die each year from HIV-related opportunistic infections for which affordable and easy-to-take medicines are still lacking.

The push for progress

Until recently, the only treatment options for children with HIV consisted of awful-tasting syrups that are difficult for kids to take. With our partners, DNDi developed an easy-to-administer '4-in-1' formulation for infants and young children. Much simpler for children and caregivers alike, it contains four antiretrovirals in one capsule of strawberry-flavoured granules that can be sprinkled on food. Our teams have also initiated work to develop improved, simpler formulations of existing treatments for cryptococcal meningitis, a leading killer of people with HIV.

Our goal is now to make sure the 4-in-1 is registered and available to children who need it, while promoting access to all available child-friendly HIV treatment formulations and to safe, effective, and affordable treatments for cryptococcal meningitis. And we continue to explore new ways to address neglected R&D needs for serious HIV-related opportunistic infections (advanced HIV) and HIV treatments for neonates, children, and adolescents.

Addressing children's unmet needs

Together with our manufacturing partner, Cipla Ltd, DNDi has completed development of a '4-in-1' combination HIV treatment specifically designed for infants and young children. The easy-to-administer, strawberry-flavoured formulation requires no refrigeration and comes in the form of granule-filled capsules that parents and caretakers can administer easily by opening the capsules and sprinkling on soft food, water, or milk. Developed with financial support from Unitaid, Agence Française de Développement (AFD),



Photo credit: Xavier Vahed-DNDi

HIV Counsellor **Thabisa Ngcaba** helps a mother give foul-tasting HIV medications to her daughter at the FAMCRU clinical research centre in Tygerberg hospital in Cape Town, South Africa. In a scene repeated across sub-Saharan Africa for years now, caregivers have struggled to give these syrups to children. Hopefully, this will soon be a scene of the past as a new generation of easy-to-take HIV treatments replace the older ones – a real revolution in care for kids living with HIV.

“ HIV management for children is still lagging behind that of adults – there are gaps in care for diagnosis and treatment.

and others, the 4-in-1 was approved by the South African Health Products Regulatory Authority in May 2022 and is currently under review by the US FDA. In Uganda, DNDi and partners completed the LOLIPOP study, with data showing a favourable safety profile in all weight bands (3-19.9 kg). The 4-in-1 was described as very easy or easy to administer by 97% of caregivers of children enrolled in the study.

We hope that the new treatment will serve as an important alternative option for children unable to be treated with dolutegravir-based paediatric regimens. Our teams are now working with partners including the Elizabeth Glaser Pediatric AIDS Foundation and Réseau EVA to ensure adoption and uptake of all optimal paediatric HIV treatments in six East and West African countries through capacity strengthening, community education, and supply chain support.

Bridging treatment gaps for a deadly HIV co-infection

Despite improvements in access to HIV antiretroviral therapy, many low- and middle-income countries (LMICs) lack access to simple, safe, and effective treatments for the deadly HIV co-infection cryptococcal meningitis. In collaboration with key partners in 2021, DNDi developed plans to address access barriers to the key WHO-recommended medicines immediate-release (IR) flucytosine (5FC) and liposomal amphotericin B (LAmB) in LMICs, including building strategic alignment among policymakers, donors, ministries of health, national implementing partners, civil society, and patient advocates. We are now working with partners to identify alternative quality-assured manufacturers of LAmB and bring at least one product to the LMIC market while monitoring progress towards improved access to reach public health targets. While IR 5FC is a critical component of first- and second-line treatments for cryptococcal meningitis, current formulations of the drug – delivered in four divided doses per day – are poorly adapted for use in resource-constrained settings. Following preparations with partners in 2021, we initiated a Phase I trial of a new sustained-release formulation of 5FC in early 2022 with the aim of delivering an affordable alternative formulation that is simpler for patients, nurses, and doctors.