

Cipla and DNDi launch child-friendly 4-in-1 antiretroviral treatment for young children living with HIV in South Africa

CAPE TOWN/MUMBAI - 14 June 2022 - The South African Health Products Regulatory Authority (SAHPRA) has approved a sweet-tasting, heat-stable, '4-in-1' fixed-dose combination of four antiretroviral (ARV) treatments composed of abacavir, lamivudine, lopinavir, and ritonavir that is specifically designed for infants and young children with HIV. This combination treatment has been developed by Cipla Limited (BSE: 500087; NSE: CIPLA EQ; and hereafter referred to as "Cipla") and the not-for-profit Drugs for Neglected Diseases *initiative* (DNDi).

This new formulation represents a significant improvement over protease inhibitor-containing paediatric ARV formulations that have been used in South Africa for decades. It does not require refrigeration, has a sweet taste and is easy to administer to infants and children of different weights and ages, a major improvement for both children and their caregivers over previously available formulations. The country has 238,000 children under the age of 15 living with HIV – the highest in the world.¹

'It is highly significant that this first regulatory approval of the 4-in-1 formulation is from a country that has a high-burden of HIV among children,' said **Dr Irene Mukui, Head of HIV, DNDi**. 'SAHPRA's accelerated review is notable and encouraging for other high-burden countries, and we acknowledge this show of commitment by the South African authorities. Now, it is our hope that all the necessary steps will be taken – first in South Africa and then in other countries – to ensure the broadest possible access to this optimal formulation for young children who need it.'

The '4-in-1' combination contains an antiretroviral combination that is recommended by the World Health Organization (WHO) as an alternative first-line regimen for infants and young children with HIV – in the form of granule-filled capsules. Caretakers will be able to give the medicine to children by sprinkling the granules over soft food like porridge or dissolving it in water or milk.

Commenting on the development, **Umang Vohra, Managing Director and Global CEO, Cipla** said, 'We are guided by our strong sense of responsibility to address unmet patient needs and we are committed to bringing novel solutions to improve lives. This approval has come at an important time when so many children are suffering from HIV at such a young age. We will continue in our endeavour to enable access to life saving solutions for all.'

¹ According to Thembisa, the leading mathematical model of the HIV epidemic in South Africa

Until recently, the only WHO-recommended lopinavir-based treatment available for babies and very young children in South Africa consisted of a syrup that contained 40% alcohol and required refrigeration. Caregivers struggled to give this bitter-tasting formulation to young children, leading to poor adherence. Caregivers without refrigeration had a very difficult time storing the formulations – sometimes burying them in the ground to keep them cold.

Now, there are multiple new child-friendly formulations of WHO-recommended regimens being introduced – including paediatric formulations of dolutegravir-containing regimens – representing a long-awaited and long overdue 'treatment revolution' for children with HIV.

'South Africa has made major advances in the treatment of adults living with HIV, but as in the rest of Africa, children with HIV have been left behind, in part because the treatment options we have are not child-friendly,' said **Professor Moherndran Archery, who represents Child and Adolescent Interests at the Southern African HIV Clinicians Society (SAHCS)**. 'Although 72% of South African adults are on life-saving HIV treatment, just half of children living with HIV in the country are on treatment. Along with other optimal ARV formulations being introduced in South Africa, the approval of the 4-in-1 is a step towards closing this gap and ending the neglect of children with HIV.'

Without treatment, half of children with HIV will die before turning two. Worldwide, 2.78 million children and adolescents are living with HIV – 88% of them in sub-Saharan Africa – but only 54% have access to treatment, according to [UNICEF](#).

Paul Miller, CEO of Cipla South Africa, said: 'For more than 20 years, Cipla has ensured equitable access to affordable, life-saving ARVs, and we are pleased to be continuing this commitment by providing optimal child-friendly antiretroviral formulations, especially for infants and young children who are at highest risk of dying without access to treatment.'

The 4-in-1 was developed and registered with the financial support of Unitaid; the French Development Agency; the Swiss Agency for Development and Cooperation; Médecins Sans Frontières International; the UBS Optimus Foundation; the Monegasque Cooperation for Development; MSF Norway; the Spanish Agency for International Development Cooperation; and other private foundations and individuals.

ENDS.

Press package

Photos of the 4-in-1 combination are available [here](#).

Media contacts

DNDi

Kim Cloete (Cape Town)

kcloete@gardp.org

+27 82 415 0736

Frédéric Ojardias (Geneva)

fojardias@dndi.org

+41 79 431 62 16

Manisha Sharma (New Delhi)

msharma@dndi.org

+91 9 711 00 90 88

Ilan Moss (New York)

imoss@dndi.org

+1 646 266 5216

Cipla

Corporate Communications

Heena Kanal

Email: CorpComm@cipla.com

About DNDi

A not-for-profit research and development organization, DNDi works to deliver new treatments for neglected patients, those living with Chagas disease, sleeping sickness (human African trypanosomiasis), leishmaniasis, filarial infections, mycetoma, paediatric HIV, and hepatitis C. DNDi is also coordinating the ANTICOV clinical trial to find treatments for mild-to-moderate COVID-19 cases in Africa. Since its inception in 2003, DNDi has delivered eleven new treatments to date, including new drug combinations for kala-azar, two fixed-dose antimalarials, and DNDi's first successfully developed new chemical entity, fexinidazole, approved in 2018 for the treatment of both stages of sleeping sickness. www.dndi.org

About Cipla

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in our home markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, anti-retroviral, urology, cardiology, anti-infective and CNS segments are well-known. Our 47 manufacturing sites around the world produce 50+ dosage forms and 1,500+ products using cutting-edge technology platforms to cater to our 80+ markets. Cipla is ranked 3rd largest in pharma in India (IQVIA MAT Mar'22), 3rd

largest in the pharma private market in South Africa (IQVIA MAT Mar'22), and is among the most dispensed generic players in the U.S.

For over eight decades, making a difference to patients has inspired every aspect of Cipla's work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS at less than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility and affordability to the centre of the HIV movement. A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring forLife' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers and all stakeholders. For more, please visit www.cipla.com, or click on [Twitter](#), [Facebook](#), [LinkedIn](#).