UNDER EMBARGO UNTIL WEDNESDAY 24 SEPTEMBER AT 7AM EST / 1PM CEST

Unitaid, CHAI, and Wits RHI enter into a landmark agreement with Dr. Reddy's to make HIV prevention tool lenacapavir affordable in LMICs

The revolutionary HIV prevention tool, injectable lenacapavir, will be available at a cost of US\$40 a year in 120 low- and middle-income countries starting in 2027, under a new partnership announced today between Dr. Reddy's Laboratories and Unitaid, the Clinton Health Access Initiative (CHAI), and Wits RHI.

Originally developed by Gilead Sciences, lenacapavir is a twice-yearly injection that has shown exceptional effectiveness in preventing HIV. Since 2010, coordinated global efforts have reduced new HIV infections by 40 percent, but UNAIDS data show 1.3 million new infections occurred in 2024. This long-acting injectable could transform HIV prevention for millions of people who struggle with daily oral pre-exposure prophylaxis (PrEP) pills. Moreover, the agreement now brings the price of the injectable on par with oral PrEP, a key condition for uptake in low- and middle-income countries.

The U.S. Food and Drug Administration and European Medicines Agency provided regulatory approvals in record time. With Unitaid's support, the World Health Organization followed suit, issuing a global recommendation for lenacapavir in July.

Today's agreement provides Dr. Reddy's with financial, technical, and regulatory support to deliver affordable, quality-assured generic versions of lenacapavir to low- and middle-income countries by 2027, following regulatory approval. That is just less than two years after the regulatory approval of Gilead's product in high-income countries. Without strategic interventions like this, making new medicines widely available in low- and middle-income countries often takes a decade or more.

This Unitaid-backed deal, with CHAI as technical lead, is part of a multi-partner, multisupplier strategy to build a competitive and sustainable market for long-acting HIV prevention. In parallel, the Gates Foundation have secured a separate agreement with another licensed manufacturer, Hetero Labs – ensuring affordable options, reliable supply, and long-term impact for communities worldwide.

"Securing a US\$40 price for the twice-yearly lenacapavir injection for PrEP is a historic breakthrough that proves the most advanced tools can be made affordable from the very start. This directly answers the calls from countries and communities to make lenacapavir as affordable as oral PrEP" said Unitaid's Executive Director Dr. Philippe Duneton. "This is exactly the kind of impact Unitaid was created to deliver. Just as we did with dolutegravir, which became the most widely used HIV treatment worldwide, we

are working with partners to ensure lenacapavir will be within reach for millions who need it most."

"The ability to protect someone for six months with a single injection, at the same cost as the currently available daily pills, is truly transformational," said President Bill Clinton, Board Chair and Co-Founder of CHAI. "This partnership marks a remarkable breakthrough and a fundamental shift in what's possible for HIV prevention. And I'm humbled that CHAI can play its part – not only confronting the epidemic, but helping give the world a genuine chance to end it."

"Our partnership for lenacapavir is a significant step in our mission to enhance global patient access and affordability to innovative treatment in the fight against HIV. The development and planned supply of a high-quality, affordable generic version of lenacapavir represents a crucial advancement in the prevention of HIV," said Deepak Sapra, Chief Executive Officer of API and Services at Dr. Reddy's Laboratories. "This partnership combines our deep science and market expertise with our partners' technical, financial and regulatory strengths. It reinforces our commitment to address the needs of underserved populations, in keeping with our ambitious goal to impact 1.5 billion patients by 2030, globally."

"Generic manufacture of lenacapavir is essential to ensure this breakthrough HIV prevention option is not limited to a privileged few," said Professor Saiqa Mullick, Director of Implementation Science at Wits RHI, University of the Witwatersrand. "By driving prices down and securing sustainable supply, generics will make six-monthly PrEP a real choice for the millions of people in great need in low- and middle-income countries."

In October 2024, <u>Gilead granted voluntary licenses</u> to six generic manufacturers, including Dr. Reddy's, to supply this product across 120 low- and middle-income countries. Efforts have also been underway to increase access in the period before generics become available. This includes a <u>landmark commitment</u> from PEPFAR and Global Fund with support from the Children's Investment Fund Foundation (CIFF), to procure lenacapavir for prevention for up to 2 million people LMICs, as reconfirmed by the Global Fund in <u>July 2025</u> and PEPFAR in <u>September 2025</u>.

Commenting on the agreements, Kate Hampton, CEO of CIFF, said: "The deals announced today on generics represent a major step forward on a sustainable pathway toward ending the HIV epidemic. They build on the funding CIFF and others have committed towards large-scale procurement of lenacapavir, and complementary investments at every stage of the value chain. Together, through multiple interventions,

partners are helping foster a competitive market, so that access to lenacapavir is affordable and reliable, for all those who need it."

Background on today's agreement

Today's agreement brings the cost of the injection to US\$40 per person per year. The lenacapavir prevention regimen also requires an initial oral dose when starting the regimen – two tablets to be taken on the day of the first injection and two tablets to be taken on the following day, to ensure protective levels of the drug are reached quickly. As part of the agreement, the price of the oral course will cost no more than US\$17, supporting affordability of the full regimen.

Dr. Reddy's is now positioned among the first generic suppliers to come to market, helping establish the competitive landscape essential for long-term success. Multiple suppliers create competition that keeps prices low, safeguards against supply disruptions, and gives countries procurement flexibility – critical factors for scaling up access effectively.

"For too long, low-income countries have waited years for access to breakthrough medicines," said Buddy Shah, CEO of CHAI. "This deal changes that – by 2027, a nearly 100% effective HIV prevention tool will be affordable and available at the same time globally. It's a new model for how innovation reaches those who need it most."

This pricing breakthrough is part of Unitaid's broader strategy to integrate lenacapavir into HIV prevention programs. The organization is supporting policy and regulatory processes while working with communities and health systems in early adopter countries to ensure rapid, effective uptake. Unitaid is also supporting real-world research through Wits RHI and Fiotec in South Africa and Brazil to answer key implementation questions about integrating lenacapavir into national HIV programs, and developing new investments to support decentralized, community-based delivery approaches across sub-Saharan Africa.

While Gilead's voluntary licenses are an important step forward, they still do not extend to all countries in need. Unitaid remains committed to addressing access barriers in countries not covered by the existing agreements.

Notes to the editor

Media contacts:

Unitaid: Kyle Wilkinson, Media Officer, wilkinsonk@unitaid.who.int, +41 79 445 17 45

CHAI: Corina Milic, Director of Communications, cmilic@clintonhealthaccess.org, +1 416 371 6313

Wits RHI: Deshni Naidoo, dnaidoo@wrhi.ac.za, +27 82 608 4485 / Susie Cornell, scornell@wrhi.ac.za, +27 79 882 7913

Dr. Reddy's Laboratories: Richa Periwal, <u>richaperiwal@drreddys.com</u>, Priya K, <u>priyak@drreddys.com</u>

About Unitaid

Unitaid saves lives by making new health products affordable and available in low- and middle-income countries. Collaborating with partners, Unitaid identifies innovative treatments, tackles market barriers, and quickly delivers solutions to those in need. Since 2006, Unitaid has unlocked over 100 health products, addressing HIV, TB, malaria, women's and children's health, and pandemic preparedness. Every year, these products benefit more than 300 million people. Unitaid is a hosted partnership of the World Health Organization. www.unitaid.org

About CHAI

The Clinton Health Access Initiative, Inc. (CHAI) is a global health organization committed to saving lives and improving health outcomes in low- and middle-income countries by enabling the government and private sector to strengthen and sustain quality health systems. For more information, please

visit: www.clintonhealthaccess.org

About Wits RHI

Wits RHI, is a research institute of the University of the Witwatersrand, established in 1994 by Professor Helen Rees to support South Africa's newly democratic government in shaping national health policies, has grown into a leading African research and implementation institute with a global reputation for innovation and responsiveness to health challenges. With a 30-year track record in investigator-led and consortia studies, Wits RHI excels in policy development and implementation across diverse populations and all phases of clinical trials. Its multidisciplinary approach integrates research, technical assistance, advocacy, and health systems strengthening to deliver impactful solutions in infectious and vaccine-preventable diseases, maternal and family health, antimicrobial resistance, and climate-related health crises. The Institute applies rigorous epidemiological and qualitative methods to identify health problems, generate evidence, and evaluate interventions in real-world settings. Its work spans vaccines, therapeutics, diagnostics, and modelling, with a focus on HIV, TB, STIs, COVID-19, influenza, Mpox,

Rotavirus, and outbreak pathogens including Poxviruses, Ebola, and Yellow Fever. www.wrhi.ac.za

About Dr. Reddy's Laboratories

Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance. For more information, log on to: www.drreddys.com