Press Release

DR. REDDY'S LABORATORIES LTD.
8-2-337, Road No. 3, Banjara Hills,
Hyderabad - 500034. Telangana, India.

CIN: L85195TG1984PLC004507
Tel: + 91 40 4900 2900
Fax: + 91 40 4900 2999
Email: mail@drreddys.com
Web: www.drreddys.com

CONTACT	
INVESTOR RELATIONS	**MEDIA RELATIONS**
AISHWARYA SITHARAM AISHWARYASITHARAM@DRREDDYS.COM	SANTOSH VYAS SANTOSHVYAS@DRREDDYS.COM

U.S. FDA grants tentative approval for Dr. Reddy's twice-yearly injectable lenacapavir, advancing access to HIV prevention across 120 countries outside the US

- ***The approval was granted under the U.S. FDA's President's Emergency Plan for AIDS Relief (PEPFAR) program.***
- ***Unitaid, Wits RHI and CHAI supported the accelerated development and regulatory pathway for twice-yearly injectable lenacapavir.***
- ***Under the existing agreement, injectable lenacapavir will be available at US$40 per person per year across 120 countries covered by Gilead's voluntary licence.***
- ***The first supplies of injectable lenacapavir are expected to reach countries before the end of 2026, with broader availability across eligible countries in 2027.***

Hyderabad, India; November 02, 2026: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY, along with its subsidiaries together referred to as "Dr. Reddy's") today announced that the U.S. Food and Drug Administration (FDA) has granted tentative approval to its long-acting injectable lenacapavir for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 77 pounds (35 kg). The approval was granted under the U.S. FDA's President's Emergency Plan for AIDS Relief (PEPFAR) program.

The approval builds on the voluntary licence granted by Gilead Sciences to Dr. Reddy's in October 2024, followed by an agreement with Unitaid, the Wits Reproductive Health and HIV Institute (Wits RHI) and the Clinton Health Access Initiative (CHAI) in September 2025 to support product development, accelerate the regulatory pathway and enable access to injectable lenacapavir at US$40 per person per year across 120 countries in Gilead's voluntary licence.

The FDA approval represents an important milestone for Dr. Reddy's Public Health Access portfolio and reflects the company's capabilities in developing and manufacturing complex medicines. The first supplies are expected to reach people by the end of 2026, with broader rollout across eligible countries expected in 2027.

HIV continues to pose a significant global public health challenge, with gaps remaining in access to and uptake of effective prevention options. Long-acting lenacapavir, administered twice a year, provides an additional prevention option for people who may face challenges with more frequently administered pre-exposure prophylaxis (PrEP).

Deepak Sapra, Chief Executive Officer, API and Services, Dr. Reddy's Laboratories Ltd., said:

"This is a moment of immense pride for all of us at Dr. Reddy's. Developing and manufacturing a complex long-acting injectable like lenacapavir at an affordable price required strong scientific capabilities and manufacturing expertise to address an urgent access need. The U.S. FDA approval validates that work and brings us a significant step closer to

making this twice-yearly HIV prevention option available to people across low- and middle-income countries. We are grateful to Gilead for the voluntary licence and to Unitaid, Wits RHI and CHAI for their support in accelerating this journey."

Dr. Philppe Duneton, Executive Director at Unitaid said:

"Unitaid's early risk-taking is helping shorten the time between a scientific breakthrough and real access in countries. With best-in-class HIV treatment, we delivered in four years what used to take ten. Now, with lenacapavir, we have helped shorten that timeline to just over a year. For young women in Africa, this translates into faster access to a groundbreaking HIV prevention option, with the potential to avert countless infections and drive meaningful change in the HIV response."

Dr. Neil Buddy Shah, CEO of CHAI said:

"For someone at risk of HIV, taking a pill every day to prevent a disease they don't have is a hard thing to ask. Two injections a year, of a product that is almost 100% effective at preventing HIV, changes that entirely. More than 125,000 people in Africa have already started on lenacapavir, and today's approval brings us closer to making it available to millions more for just $40 a year. Getting a generic approved just 16 months after the originator, rather than a decade later, shows what's possible when we prioritize access from the start. This should be the new standard for global health."

Professor Saiqa Mullick, Director of Implementation Science at Wits RHI, University of the Witwatersrand said:

"Generic lenacapavir has the potential to transform HIV prevention, and this is a significant milestone, but an affordable drug alone is not enough. Countries need health systems that are ready to deliver new prevention options, providers who are confident in offering them, and communities that are engaged as partners in their introduction and scale-up. Bringing these elements together will be critical to ensuring equitable access and impact."

FDA approval provides an important regulatory basis for the remaining steps towards wider availability, including WHO prequalification and national regulatory approvals. Unitaid and partners are supporting countries and communities with product introduction and scale-up, including community engagement and real-world evidence generation to inform how lenacapavir can effectively reach diverse and underserved populations.

About lenacapavir

Lenacapavir is a first-in-class, long-acting HIV-1 capsid inhibitor with a novel mechanism of action. The multi-stage mechanism of action of lenacapavir is distinguishable from other currently approved classes of antiviral agents. While most antivirals act on just one stage of viral replication, lenacapavir is designed to inhibit HIV at multiple stages of its lifecycle and has no known cross-resistance exhibited in vitro to other existing drug classes.

Lenacapavir's long-acting properties enable extended dosing intervals, representing an important advancement in the evolution of HIV medicines. It has been developed for both HIV treatment and prevention applications, with different formulations and dosing approaches depending on the intended use. WHO also recommends twice-yearly lenacapavir in its guidelines for HIV prevention.

Lenacapavir was originally developed by Gilead Sciences and is being evaluated as a long-acting option in multiple ongoing and planned early and late-stage clinical studies in Gilead's HIV prevention and treatment research program, including a once-yearly injection for HIV prevention. Lenacapavir is being developed as a foundation for potential future HIV therapies with the goal of offering both long-acting oral and injectable options with several dosing frequencies, in combination or as a mono agent, that help address individual needs and preferences of people and communities affected by HIV. The journal *Science* named lenacapavir its 2024 'Breakthrough of the Year.'

HIV-negative status must be confirmed before initiating lenacapavir and before subsequent injections, consistent with the approved Prescribing Information.

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:** Susie Cornell, scornell@wrhi.ac.za, +27 79 882 7913 / Deshni Naidoo, dnaidoo@wrhi.ac.za, +27 82 608 4485
- **Dr. Reddy's Laboratories**: Aishwarya Sitharam, aishwaryasitharam@drreddys.com, Santosh Vyas, santoshvyas@drreddys.com

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: 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.

……

Disclaimer: This press release may include statements of future expectations and other forward-looking statements that are based on the management's current views and assumptions and involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. In addition to statements which are forward-looking by reason of context, the words "may", "will", "should", "expects", "plans", "intends", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" and similar expressions identify forward-looking statements. Actual results, performance or events may differ materially from those in such statements due to without limitation, (i) general economic conditions such as performance of financial markets, credit defaults , currency exchange rates, interest rates, persistency levels and frequency / severity of insured loss events, (ii) mortality and morbidity levels and trends, (iii) changing levels of competition and general competitive factors, (iv) changes in laws and regulations and in the policies of central banks and/or governments, (v) the impact of acquisitions or reorganization, including related integration issues, and (vi) the susceptibility of our industry and the markets addressed by our, and our customers', products and services to economic downturns as a result of natural disasters, epidemics, pandemics or other widespread illness, including coronavirus (or COVID-19), and (vii) other risks and uncertainties identified in our public filings with the Securities and Exchange Commission, including those listed under the "Risk Factors" and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2026. The company assumes no obligation to update any information contained herein.