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Dr. Reddy's Laboratories announces approval for Lenalidomide Capsules from the U.S. Food and Drug Administration (USFDA)

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For Immediate Release

Hyderabad, India and Princeton, NJ, USA. October 19, 2021 - 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 the final approval of its Abbreviated New Drug Application (ANDA) for Lenalidomide Capsules, in 2.5 mg and 20 mg strengths, and tentative approval for 5 mg, 10 mg, 15 mg, and 25 mg strengths, a therapeutic equivalent generic version of REVLIMID® (lenalidomide) Capsules, from the U.S. Food and Drug Administration (USFDA). With this approval, Dr. Reddy's is eligible for 180 days of generic drug exclusivity for Lenalidomide Capsules, 2.5 mg and 20 mg.

In September 2020, [Dr. Reddy's announced a settlement agreement](#) of their litigation with Celgene, the maker of REVLIMID® (lenalidomide) Capsules and a wholly-owned subsidiary of Bristol Myers Squibb (NYSE: BMY), relating to patents for the branded drug.

In settlement of all outstanding claims in the litigation, Celgene agreed to provide Dr. Reddy's with a license to sell volume-limited amounts of generic lenalidomide capsules in the U.S. beginning on a confidential date after March 2022 subject to regulatory approval. The agreed-upon percentages remain confidential. As part of the settlement, Dr. Reddy's is also licensed to sell generic lenalidomide capsules in the U.S. without volume limitation beginning on January 31, 2026.

"We are pleased with the Agency's approval of Lenalidomide Capsules, 2.5 mg and 20 mg and being eligible for 180-day market exclusivity," says Marc Kikuchi, CEO, North America Generics, Dr. Reddy's Laboratories. "We look forward to bringing a more affordable generic version of this drug to market for the benefit of patients."

Please refer to Lenalidomide Capsules 2.5 mg and 20 mg Package Insert for Black Box warning and important safety information. Please click here for full prescribing information:

<https://www.drreddys.com/pi/final-25mg-20mg.pdf>

**WARNING: EMBRYO-FETAL TOXICITY, HEMATOLOGIC TOXICITY, and
VENOUS and ARTERIAL THROMBOEMBOLISM**

Embryo-Fetal Toxicity

Do not use lenalidomide capsules during pregnancy. Lenalidomide, a thalidomide analogue, caused limb abnormalities in a developmental monkey study. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide capsules are used during pregnancy, it may cause birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting lenalidomide treatment. Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after lenalidomide treatment [see *Warnings and Precautions (5.1)*, and *Medication Guide (17)*]. To avoid embryo-fetal exposure to lenalidomide, lenalidomide capsules are only available through a restricted distribution program, the PS-Lenalidomide Shared REMS Program (5.2).

Information about the PS-Lenalidomide Shared REMS Program is available at www.PS-LenalidomideSharedREMS.com or by calling at 1-866-496-0807.

Hematologic Toxicity (Neutropenia and Thrombocytopenia)

Lenalidomide can cause significant neutropenia and thrombocytopenia. Eighty percent of patients with del 5q myelodysplastic syndromes had to have a dose delay/reduction during the major study. Thirty-four percent of patients had to have a second dose delay/reduction. Grade 3 or 4 hematologic toxicity was seen in 80% of patients enrolled in the study. Patients on therapy for del 5q myelodysplastic syndromes should have their complete blood counts monitored weekly for the first 8 weeks of therapy and at least monthly thereafter. Patients may require dose interruption and/or reduction. Patients may require use of blood product support and/or growth factors [see *Dosage and Administration (2.2)*].

Venous and Arterial Thromboembolism

Lenalidomide has demonstrated a significantly increased risk of deep vein thrombosis (DVT) and pulmonary embolism (PE), as well as risk of myocardial infarction and stroke in patients with multiple myeloma who were treated with lenalidomide and dexamethasone therapy. Monitor for and advise patients about signs and symptoms of thromboembolism. Advise patients to seek immediate medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Thromboprophylaxis is recommended and the choice of regimen should be based on an assessment of the patient's underlying risks [see *Warnings and Precautions (5.4)*].

Revlimid® is a trademark of Celgene, a wholly-owned subsidiary of Bristol Myers Squibb.

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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. 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, 2021. The company assumes no obligation to update any information contained herein.