Press Release

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

CONTACT	
INVESTOR RELATIONS	**MEDIA RELATIONS**
AMIT AGARWAL AMITA@DRREDDYS.COM	USHA IYER USHAIYER@DRREDDYS.COM

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

Hyderabad, India, October 19, 2021 **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)].*

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