Press Release

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Dr. Reddy's Laboratories announces the launch of Lenalidomide Capsules in the U.S. with two of six strengths eligible for first-to-market, 180-day exclusivity

Hyderabad, India and Princeton, NJ, USA. September 7, 2022 — 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 launch, in the U.S. market, of Lenalidomide Capsules, a therapeutic equivalent generic version of REVLIMID® (lenalidomide) Capsules approved by U. S. Food and Drug Administration (USFDA). With this volume-limited launch, Dr. Reddy's is eligible for first-to-market, 180 days of generic drug exclusivity for Lenalidomide Capsules in 2.5 mg and 20 mg strengths.

"We are pleased with the first-to-market launch of two of our six strengths of Lenalidomide Capsules with 180-day market exclusivity," says Marc Kikuchi, CEO, North America Generics, Dr. Reddy's Laboratories. "Bringing a more affordable generic version to market creates greater patient access for this important drug."

As previously announced, Celgene agreed to provide Dr. Reddy's with a license to sell volume-limited amounts of generic lenalidomide capsules in the U.S. in settlement of all outstanding claims of its litigation. 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.

Dr. Reddy's Lenalidomide Capsules are available in strengths of 2.5 mg, 5 mg, and 10 mg, each in a bottle-count size of 28, as well as 15 mg, 20 mg, and 25 mg strengths, each in a bottle-count size of 21.

Please click here to see the full prescribing information, along with boxed warning for Dr. Reddy's Lenalidomide Capsules.

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

See full prescribing information for complete boxed warning.

EMBRYO-FETAL TOXICITY

- Lenalidomide, a thalidomide analogue, caused limb abnormalities in a developmental monkey study similar to birth defects caused by thalidomide in humans. If lenalidomide is used during pregnancy, it may cause birth defects or embryo-fetal death.
- Pregnancy must be excluded before start of treatment. Prevent pregnancy during treatment by the use of two reliable methods of contraception.

Lenalidomide capsules are available only through a restricted distribution program, called the Lenalidomide REMS program.

HEMATOLOGIC TOXICITY.
Lenalidomide can cause significant neutropenia and thrombocytopenia.

VENOUS AND ARTERIAL THROMBOEMBOLISM

- 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 receiving lenalidomide with dexamethasone. Anti-thrombotic prophylaxis is recommended.

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. 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