



## CIPLA RECEIVES USFDA APPROVAL FOR GENERIC VERSION OF REVLIMID® (LENALIDOMIDE CAPSULES)

**Mumbai, India/ New Jersey, United States, September 7, 2022:** Cipla Limited (BSE: 500087; NSE: CIPLA EQ) ("Cipla") announced that it has received final approval for its Abbreviated New Drug Application (ANDA) for Lenalidomide Capsule 5 mg, 10 mg, 15 mg and 25 mg from the United States Food and Drug Administration (US FDA).

Cipla's Lenalidomide Capsules are the AB-rated therapeutic equivalent generic version of Bristol Myers Squibb's (Celgene) Revlimid® (Lenalidomide) Capsules.

Lenalidomide is an immunomodulatory prescription drug which is indicated for several hematological malignancies in adults such as Multiple Myeloma, Myelodysplastic syndromes, Mantle cell lymphoma, Follicular lymphoma, and Marginal Zone lymphoma. Depending on the type of cancer, it can be used as monotherapy or combination as a part of first line regimen, maintenance regimen or relapsed settings.

Lenalidomide capsules are not to be used in pregnant women. It is not known if lenalidomide is safe and effective in children. Lenalidomide Capsules should not be used to treat people with chronic lymphocytic leukemia (CLL) outside of a controlled clinical trial.

According to IQVIA (IMS Health), Revlimid® (Lenalidomide) Capsules had US sales of approximately **\$ 2.58 billion** for the 12-month period ending **June 2022**.

The product will be available for shipping soon.

### About Cipla:

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in our home markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, anti-retroviral, urology, cardiology, anti-infective and CNS segments are well-known. Our 47 manufacturing sites around the world produce 50+ dosage forms and 1,500+ products using cutting-edge technology platforms to cater to our 80+ markets. Cipla is ranked 3rd largest in pharma in India (IQVIA MAT June'22), 3rd largest in the pharma private market in South Africa (IQVIA MAT June'22), and is among the most dispensed generic players in the U.S. For over eight decades, making a difference to patients has inspired every aspect of Cipla's work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS at less than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility, and affordability to the centre of the HIV movement. A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring forLife' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers and all stakeholders. For more, please visit [www.cipla.com](http://www.cipla.com), or click on [Twitter](#), [Facebook](#), [LinkedIn](#).

### ABOUT REVLIMID®

Cipla Ltd.

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In the U.S., REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma. REVLIMID® as a single agent is also indicated as a maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplant. REVLIMID® is indicated for patients with transfusion dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. REVLIMID® is approved in the U.S. for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. Limitations of Use: REVLIMID® is not indicated and is not recommended for the treatment of chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

### **ABOUT BRISTOL MYERS SQUIBB**

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol Myers Squibb, visit us at [BMS.com](http://BMS.com) or follow us on [LinkedIn](#), [Twitter](#), [YouTube](#), [Facebook](#) and [Instagram](#).

Celgene and Juno Therapeutics are wholly owned subsidiaries of Bristol Myers Squibb company. In certain countries outside the U.S., due to local laws, Celgene and Juno Therapeutics are referred to as, Celgene, a Bristol Myers Squibb company and Juno Therapeutics, a Bristol Myers Squibb company.

### **ABOUT CELGENE**

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global pharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through gene and protein regulation. For more information, please visit the Company's website at [www.celgene.com](http://www.celgene.com). Follow Celgene on Social Media: [@Celgene](#), [Pinterest](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

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