Zydus receives final approval from the USFDA for Lenalidomide Capsules 5 mg, 10 mg, 15 mg and 25 mg

Receives tentative approval for 2.5 mg and 20 mg strengths

Ahmedabad, India, 13 September, 2022

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) has received approval from the United States Food and Drug Administration (USFDA) to market Lenalidomide Capsules, USP 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg. The company has received final approvals for 5 mg, 10 mg, 15 mg and 25 mg strengths and tentative approvals for 2.5 mg and 20 mg strength. USRLD: Revlimid®.

Lenalidomide is used to treat various types of cancers. It works by slowing or stopping the growth of cancer cells. It is also used to treat anemia in patients with certain blood/bone marrow disorders (myelodysplastic syndromes-MDS). The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Speaking on the development Dr. Sharvil Patel, Managing Director, Zydus Lifesciences said, "We remain focused on providing patients access to affordable medication and USFDA approval of Lenalidomide Capsules, an important oncology therapy product is yet another step in this endeavour. This underscores our mission to offer quality healthcare solutions that impact lives as we continue to explore opportunities to grow our US business."

Lenalidomide had annual sales of USD 2.86 bn in the United States, according to IQVIA MAT July 2022. The product would be launched in the US market soon.

The group now has 322 approvals and has so far filed over 428* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th June 2022)*

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PRESS RELEASE

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