

Zydus receives final approval from the USFDA for Lenalidomide Capsules, 2.5 mg and 20 mg

Ahmedabad, India, 7 March, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as “Zydus”) has received final approval from the United States Food and Drug Administration (USFDA) for Lenalidomide Capsules, 2.5 mg and 20 mg (USRLD: Revlimid[®] Capsules).

Lenalidomide Capsules are 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). Lenalidomide may lessen the need for blood transfusions. The products will be launched in the US market shortly. The drugs will be manufactured at the group’s formulation manufacturing facility in SEZ, Ahmedabad (India).

Lenalidomide Capsules had annual sales of USD 183 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 349 approvals and has so far filed over 440* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2022)



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