Zydus receives final approval from USFDA for Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg

Ahmedabad, India, 5 March, 2025

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) to manufacture Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg. (USRLD: Sprycel® Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg).

Dasatinib is indicated for the treatment of newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukaemia (CML) in chronic phase. It is also used to treat adults with chronic, accelerated or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib and adults with Philadelphia chromosome-positive acute lymphoblastic leukaemia (Ph+ ALL) with resistance or intolerance to prior therapy. Dasatinib tablets will be produced at Zydus Lifesciences Ltd (SEZ), Ahmedabad.

Dasatinib tablets had annual sales of USD 1807.7mn in the United States (IQVIA MAT January 2025).

The group now has 415 approvals and has so far filed 483* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31st December, 2024.)*

PRESS RELEASE

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