Zydus receives tentative approval from USFDA for Ibrutinib tablets 140 mg, 280 mg, and 420 mg

Ahmedabad, India, 24 July, 2025

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as "Zydus") has received tentative approval from the United States Food and Drug Administration (USFDA) for Ibrutinib tablets 140 mg, 280 mg, and 420 mg (USRLD: Imbruvica® tablets, 140 mg, 280 mg and 420 mg).

Ibrutinib is a kinase inhibitor indicated for the treatment of adult patients with Chronic lymphocytic leukaemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion, and Waldenstrom's macroglobulinemia (WM).

Ibrutinib tablets will be produced at Zydus Lifesciences Ltd (SEZ), Ahmedabad. Ibrutinib tablets had annual sales of USD 2148.9 mn in the United States (IQVIA MAT May 2025).

The group now has 420 approvals and has so far filed 484* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 30th June 2025)*

PRESS RELEASE

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