



July 24, 2025

BSE Limited

P J Towers,
Dalal Street,
Mumbai-400001

Code: 532321

National Stock Exchange of India Limited

Exchange Plaza,
C/1, Block G,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Code: Zyduslife

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated July 24, 2025, titled **“Zydus receives tentative approval from USFDA for Ibrutinib tablets 140 mg, 280 mg, and 420 mg”**.

The contents of the press release give full details.

Please bring the aforesaid news to the notice of the members of the exchange and the investors' at large.

Yours faithfully,
For, **ZYDUS LIFESCIENCES LIMITED**

DHAVAL N. SONI
COMPANY SECRETARY AND COMPLIANCE OFFICER
MEMBERSHIP NO. FCS7063

Encl.: As above

Zydus Lifesciences Limited

Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle,
S. G. Highway, Ahmedabad-382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000
website : www.zyduslife.com | CIN : L24230GJ1995PLC025878



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**

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited

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