



Dedicated To Life

March 16, 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 March 16, 2025, titled "**Zydus receives final approval from USFDA for Eluxadoline Tablets, 75 mg and 100 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.

The submission of press release got delayed as stakeholders spread across global time zones.

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 final approval from USFDA for Eluxadoline Tablets, 75 mg and 100 mg

Ahmedabad, India, 16 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 Eluxadoline Tablets, 75 mg and 100 mg (USRLD: Viberzi® Tablets, 75 mg and 100 mg).

Eluxadoline is a mu-opioid receptor agonist, indicated in adults for the treatment of irritable bowel syndrome with diarrhoea (IBS-D). Eluxadoline tablets will be produced at Zydus Lifesciences Ltd (SEZ), Ahmedabad.

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Eluxadoline Tablets, 75 mg and 100 mg. With this approval, Zydus is eligible for 180 days of shared generic drug exclusivity for Eluxadoline Tablets, 75 mg and 100 mg.

Eluxadoline tablets had annual sales of USD 243.7 mn in the United States (IQVIA MAT January 2025).

The group now has 419 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**

For further information please contact :
The Corporate Communications Department

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