



August 9, 2024

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 August 9, 2024 titled **"Zydus receives final approval from USFDA for Valbenazine Capsules"**.

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 we had to consult our IR head and seek his advise across global time zones in India and US.

Thanking you,

Yours faithfully,

For, **ZYDUS LIFESCIENCES LIMITED**

DHAVAL N. SONI
COMPANY SECRETARY

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 Valbenazine Capsules

Ahmedabad, India, 9 August, 2024

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 market Valbenazine Capsules, 40 mg, 60 mg, and 80 mg (USRLD: Ingrezza[®] Capsules).

Valbenazine Capsules are indicated for the treatment of adults with tardive dyskinesia (uncontrollable movement of the face, tongue, or other body parts). The drug will be manufactured at the group’s formulation manufacturing facility in Ahmedabad SEZ - II, India.

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Valbenazine Capsules, 40 mg, and 80 mg, and was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Valbenazine Capsules, 60 mg. With this approval, Zydus is eligible for 180 days of shared generic drug exclusivity for Valbenazine Capsules, 40 mg, and 80 mg, and is eligible for 180 days of sole generic drug exclusivity for Valbenazine Capsules, 60 mg.

Valbenazine Capsules had annual sales of USD 1993.6 mn in the United States (IQVIA MAT June 2024).

The group now has 400 approvals and has so far filed over 465* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th June 2024)*



**PRESS
RELEASE**

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited

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