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

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