Zydus receives final approval from USFDA for Isotretinoin Capsules USP, 10 mg 20 mg, 25 mg, 30 mg, 35 mg and 40 mg

Ahmedabad, India, 23 May, 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) Isotretinoin capsules USP, 10 mg 20 mg, 25 mg, 30 mg, 35 mg and 40 mg (USRLD: Absorica® Capsules, 10 mg, 20 mg, 25 mg, 30 mg, 35 mg and 40 mg).

Isotretinoin capsules are indicated to treat severe, disfiguring nodular acne. Isotretinoin capsules will be produced at the Group's manufacturing site at Moraiya, Ahmedabad.

Isotretinoin capsules had annual sales of USD 115.4 mn in the United States (IQVIA MAT March 2025).

The group now has 427 approvals and has so far filed 492* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31st March, 2025.)*

PRESS RELEASE

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