Zydus receives tentative approval from USFDA for Budesonide delayed-release capsules, 4 mg

Ahmedabad, India, 04 November, 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 Budesonide delayed-release capsules, 4 mg (USRLD: Tarpeyo Capsules, 4 mg).

Budesonide is indicated for mild to moderate active Crohn's disease involving the ileum and/or the ascending colon in adults and children 8 years of age and older. Budesonide capsules will be produced at is Zydus Pharmaceuticals Ltd, SEZ-II.

The group now has 425 approvals and has so far filed 487* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 30-Sept-25)*

PRESS RELEASE

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