# 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

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