Zydus receives final approval from USFDA for Enzalutamide Capsules, 40 mg

Ahmedabad, India, 28 September, 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 manufacture Enzalutamide Capsules, 40 mg (USRLD: Xtandi® Capsules, 40 mg).

Enzalutamide capsules are androgen receptor inhibitors indicated for the treatment of patients with metastatic castration-resistant prostate cancer. Enzalutamide Capsules will be produced at the Group's manufacturing site at Moraiya, Ahmedabad.

Enzalutamide capsules, 40 mg had annual sales of USD 869.4 mn in the United States (IQVIA MAT July 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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