Zydus receives tentative approval from USFDA for Enzalutamide Tablets, 40 mg and 80 mg

Ahmedabad, India, 02 October, 2024

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) to manufacture Enzalutamide Tablets, 40 mg and 80 mg (USRLD: Xtandi® Tablets, 40 mg, 80 mg).

Enzalutamide tablets are androgen receptor inhibitors indicated for the treatment of patients with castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. Enzalutamide Tablets will be produced at the Group's manufacturing site at SEZ, Ahmedabad.

Enzalutamide tablets, 40 mg and 80 mg had annual sales of USD 1417.2 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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