

Zydus receives Final Approvals from the USFDA for Pimavanserin Capsules, 34 mg and Pimavanserin Tablets, 10 mg

Ahmedabad, India, January 17, 2024

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as “Zydus”) has received final approvals from the United States Food and Drug Administration (USFDA) to manufacture and market Pimavanserin Capsules, 34 mg (USRLD: Nuplazid[®] Capsules) and Pimavanserin Tablets, 10 mg (USRLD: Nuplazid[®] Tablets), respectively.

Pimavanserin is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson disease psychosis. Both the tablets and the capsules will be manufactured at the group’s formulation manufacturing facility at Ahmedabad SEZ, India.

Pimavanserin Capsules, 34 mg had annual sales of USD 149 mn and Pimavanserin Tablets, 10 mg had annual sales of USD 10 mn in the United States (IQVIA Dec. Nov. 2023).

The group now has 384 approvals and has so far filed over 448* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 30th September 2023)

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