Zydus receives final approval from USFDA for Paliperidone Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg

Ahmedabad, India, 10 October, 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 Paliperidone Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg (USRLD: Invega Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg).

Paliperidone extended-release tablets are indicated for the acute and maintenance treatment of schizophrenia, acute treatment of schizoaffective disorder as monotherapy and acute treatment of schizoaffective disorder as an adjunct to mood stabilizers and/or antidepressants. Paliperidone extended-release tablets will be produced at the Group's manufacturing site at SEZ, Ahmedabad.

Paliperidone extended-release tablets had annual sales of USD 47.1 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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