Zydus receives final approval from the USFDA for Lacosamide Tablets

Ahmedabad, India, 16 December, 2023

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 and market Lacosamide Tablets USP, 50 mg, 100 mg, 150 mg, and 200 mg (USRLD: Vimpat® Tablets).

Lacosamide is indicated to treat partial-onset seizures. It is also used with other medicines to treat primary generalized tonic-clonic seizures. The product will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Lacosamide Tablets USP, 50 mg, 100 mg, 150 mg, and 200 mg had annual sales of USD 249 mn in the United States (IQVIA Dec. Oct. 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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PRESS RELEASE

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