Zydus receives Final Approval from the USFDA for Gabapentin Tablets (Once-Daily), 300 mg and 600 mg

The company is the first to receive the final approval for generic tablets

Ahmedabad, India, January 25, 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 and market Gabapentin Tablets (Once-Daily), 300 mg and 600 mg (USRLD: Gralise® Tablets). Zydus is the first company to receive final approval for generic Gabapentin Tablets (Once-Daily), 300 mg and 600 mg. Following approval, the product will be launched immediately in the US.

Gabapentin is indicated for the management of Postherpetic Neuraligia (PHN). The product will be manufactured at the group's formulation manufacturing facility at Moraiya, Ahmedabad. Gabapentin Tablets (Once-Daily), 300 mg and 600 mg had annual sales of USD 85 mn in the United States (IQVIA 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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PRESS RELEASE

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