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

Ahmedabad, India, 20 February, 2023

Zydus Lifesciences Limited's (including its subsidiaries/affiliates hereafter referred to as "Zydus") subsidiary Zydus Pharmaceuticals (USA) Inc. has received tentative approval from the United States Food and Drug Administration (USFDA) for Gabapentin Tablets (Once-Daily), 300 mg and 600 mg (USRLD: Gralise® Tablets).

Gabapentin tablets are indicated for the management of Postherpetic Neuralgia (PHN). The drug will be manufactured at the group's formulation manufacturing facility at Moraiya.

Gabapentin Tablets had annual sales of USD 90 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 343 approvals and has so far filed over 440* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2022)

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PRESS RELEASE

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