Zydus receives tentative approval from the USFDA for Levomilnacipran Extended-Release Capsules

Ahmedabad, India, 16 January, 2023

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) subsidiary Zydus Pharmaceuticals (USA) Inc. (Zydus) has received tentative approval from the United States Food and Drug Administration (USFDA) to market Levomilnacipran Extended-Release Capsules, 20 mg, 40 mg, 80 mg, and 120 mg (USRLD: Fetzima® Extended-Release Capsules).

Levomilnacipran is a serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of Major Depressive Disorder (MDD) in adults. The drug will be manufactured at the group's formulation manufacturing facility at Moraiya, Ahmedabad, India.

Levomilnacipran Extended-Release Capsules had annual sales of USD 85 million in the United States according to IQVIA data (IQVIA MAT Sept. 2022).

The group now has 341 approvals and has so far filed over 431* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th September 2022)*

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PRESS RELEASE

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