Zydus receives two final approvals from the USFDA for Venlafaxine Extended-Release Tablets and Pregabalin Extended-Release Tablets

Ahmedabad, India, 31 August, 2022

Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited) has received final approval from the United States Food and Drug Administration (USFDA) to market Venlafaxine Extended-Release Tablets, USP 37.5 mg, 75 mg, 150 mg and 225 mg. USRLD: Venlafaxine Hydrochloride Extended-Release Tablets. The company also received the final approval from USFDA to market Pregabalin Extended-Release Tablets, USP 82.5 mg, 165 mg and 330 mg. USRLD: Lyrica CR.

Venlafaxine is used to treat depression, anxiety, panic attacks and social anxiety disorder. It is expected to improve mood and energy levels in patients. The medication is also expected to decrease fear, anxiety, unwanted thoughts and the number of panic attacks. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Venlafaxine Extended-Release tablets had annual sales of USD 46 mn in the United States according to IQVIA MAT July 2022.

Pregabalin Extended-Release tablets are used to treat pain caused by nerve damage due to diabetes or shingles (herpes zoster) infection. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Pregabalin Extended-Release tablets had annual sales of USD 3 mn in the United States according to IQVIA MAT June 2022.

The group now has 322 approvals and has so far filed over 428* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th June 2022)*

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PRESS RELEASE

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