Zydus receives final approval from the USFDA for Topiramate Extended-Release Capsules

Ahmedabad, India, 1 December, 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 Topiramate Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg (USRLD: Qudexy® XR Extended-Release capsules).

Topiramate Extended-Release capsule is indicated to prevent and control seizures in people with epilepsy. It may also be used to prevent migraine headaches. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Topiramate Extended-Release capsule had annual sales of USD 68.8 mn in the United States according to IQVIA data (IQVIA MAT Sep 2022).

The group now has 335 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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