Zydus receives final approval from the USFDA for Vigabatrin for Oral Solution USP, 500 mg

Ahmedabad, India, 3 March, 2023

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) for Vigabatrin for Oral Solution USP, 500 mg (USRLD: Sabril® for Oral Solution).

Vigabatrin for oral solution is indicated for the treatment of Refractory Complex Partial Seizures as adjunctive therapy in patients 2 years of age and older. It is also used to treat infantile spasms in babies and children between the ages of 1 month and 2 years. The drug will be manufactured at the group's formulation manufacturing facility at Moraiya, Ahmedabad (India).

Vigabatrin for Oral Solution USP, 500 mg had annual sales of USD 233.7 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 349 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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