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

Ahmedabad, India, 04 October, 2022

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) U.S. subsidiary Zydus Pharmaceuticals (USA) Inc. has received tentative approval from the United States Food and Drug Administration (USFDA) to market Amantadine Extended-Release Capsules USP 68.5 mg and 137 mg (USRLD: Gocovri®).

Amantadine is indicated for the treatment of dyskinesia (sudden uncontrolled movements) in patients with Parkinson's disease who are treated with levodopa therapy, with or without dopaminergic medicines. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Amantadine Extended-Release Capsules had annual sales of USD 2.7 mn in the United States according to IQVIA data (IQVIA MAT Aug 2022).

The group now has 325 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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