Zydus receives tentative approval from USFDA for Diroximel Fumarate Delayed-Release Capsules, 231 mg

Ahmedabad, India, 10 July, 2024

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as "Zydus") has received tentative approval from the United States Food and Drug Administration (USFDA) to market Diroximel Fumarate Delayed-Release Capsules, 231 mg (USRLD: Vumerity® Delayed-Release Capsules tablets).

Diroximel Fumarate Delayed-Release Capsules is indicated for the treatment of relapsing forms of multiple sclerosis (MS) in adults. The drug will be manufactured at the group's formulation manufacturing facility in Ahmedabad SEZ, India.

Diroximel Fumarate Delayed-Release Capsules had annual sales of USD 847.4 mn in the United States (IQVIA MAT May 2024).

The group now has 398 approvals and has so far filed over 460* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 31st March 2024)*

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PRESS RELEASE

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