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

Ahmedabad, India, 13 November, 2025

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 Diroximel Fumarate delayed-release capsules, 231 mg (USRLD: Vumerity Delayed-Release Capsules, 231 mg).

Diroximel fumarate delayed-release capsules, 231 mg, are indicated for the treatment of relapsing forms of multiple sclerosis (MS) in adults. Diroximel fumarate delayed-release capsules will be produced at Zydus Lifesciences Ltd, SEZ.

Diroximel fumarate delayed-release capsules had annual sales of USD 999.4 mn in the United States (IQVIA MAT Sept-2025).

The group now has 426 approvals and has so far filed 487* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 30-Sept-25)*

PRESS RELEASE

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