Zydus receives tentative approval from USFDA for Letermovir Tablets, 240 mg and 480 mg

Ahmedabad, India, 23 March, 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 Letermovir tablets, 240 mg and 480 mg, (USRLD: Prevymis® tablets).

Letermovir tablets are used to prevent disease caused by a virus called cytomegalovirus (CMV) in people who have received a bone marrow transplant or kidney transplant. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Letermovir tablets, 240 mg and 480 mg had annual sales of USD 289.5 mn in the United States (IQVIA MAT Jan-24).

The group now has 393 approvals and has so far filed over 460* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 31st December 2023)*

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PRESS RELEASE

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