Zydus receives final approval from the USFDA for Olanzapine Orally Disintegrating Tablets USP, 5 mg, 10 mg, 15 mg, and 20 mg

Ahmedabad, India, 11 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) to manufacture and market Olanzapine Orally Disintegrating Tablets USP, 5 mg, 10 mg, 15 mg, and 20 mg (USRLD: Zyprexa Zydis Orally Disintegrating Tablets).

Olanzapine Orally Disintegrating Tablets USP, 5 mg, 10 mg, 15 mg, and 20 mg are used to treat certain mental/mood conditions (such as schizophrenia and bipolar disorder). Olanzapine tablets may also be used in combination with other medication to treat depression. These tablets belong to a class of drugs called as atypical antipsychotics and work by helping to restore the balance of certain natural substances in the brain. The products will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Olanzapine Orally Disintegrating Tablets USP, 5 mg, 10 mg, 15 mg, and 20 mg had annual sales of USD 28.3 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 351 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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