

Zydus receives final approval from the USFDA for Plerixafor Injection USP, 24 mg/1.2 mL (20 mg/mL), Single-Dose Vial

Ahmedabad, India, 27 July, 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) for Plerixafor Injection, 24 mg/1.2 mL (20 mg/mL), Single-Dose Vial (USRLD: Mozobil[®] Injection, 24 mg/1.2 mL [20 mg/mL]).

Plerixafor is used by patients with certain types of cancer (non-Hodgkin's lymphoma-NHL, multiple myeloma-MM) to prepare them for stem cell transplant. The drug will be manufactured at the group's injectable manufacturing facility of Zydus Lifesciences Ltd. (Alidac) at SEZ, Ahmedabad (India).

Plerixafor Injection, 24 mg/1.2 mL (20 mg/mL), Single-Dose Vial had annual sales of USD 210 mn in the United States (IQVIA MAT May 2023).

The group now has 374 approvals and has so far filed over 442* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st March 2023)

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