Zydus receives final approval from the USFDA for Ephedrine Sulfate Injection

Ahmedabad, India, 17 May, 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 Ephedrine Sulfate Injection USP, 50 mg/mL single-dose vials (USRLD: Akovaz® Injection).

Ephedrine Sulfate Injection is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. The drug will be manufactured at the group's injectable manufacturing facility at Jarod, near Vadodara (India).

Ephedrine Sulfate Injection USP, 50 mg/mL had annual sales of USD 52 mn in the United States (IQVIA MAT Mar. 2023).

The group now has 368 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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