Zydus receives final approval from the USFDA for Norepinephrine Bitartrate Injection

Ahmedabad, India, 21 July, 2022

Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited), has received final approval from the United States Food and Drug Administration (USFDA) to market Norepinephrine Bitartrate Injection USP,4 mg/4 mL (1 mg/mL) Single-Dose Vial. (USRLD: Levophed).

Norepinephrine Bitartrate is indicated for restoration of blood pressure in adult patients with acute hypotensive state. The drug will be manufactured at the group's topical injectable manufacturing facility at Jarod, India.

Norepinephrine Bitartrate Injection USP, 1mg/1 mL had annual sales of US$ 63.8 million in the United States according to IQVIA data (IQVIA MAT May 2022).

The group now has 317 approvals and has so far filed over 420* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 31st March 2022)*

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PRESS RELEASE

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