Zydus receives final approval from the USFDA for Isoproterenol Hydrochloride Injection

Ahmedabad, India, 15 April, 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 Isoproterenol Hydrochloride Injection USP, 0.2 mg/mL and 1 mg/5 mL (0.2 mg/mL) single-dose vials (USRLD: Isuprel® Injection).

Isoproterenol hydrochloride injection is indicated to improve hemodynamic status in patients in distributive shock and shock due to reduced cardiac output and for treatment of bronchospasm occurring during anaesthesia. The drug will be manufactured at the group's injectable manufacturing facility at Jarod, near Vadodara (India).

Isoproterenol Hydrochloride Injection USP, 0.2 mg/mL and 1 mg/5 mL (0.2 mg/mL) had annual sales of USD 28.5 mn in the United States (IQVIA MAT Feb. 2023).

The group now has 362 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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