Zydus receives tentative approval from the USFDA for Sugammadex Injection

Ahmedabad, India, 16 September, 2022

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) U.S. subsidiary Zydus Pharmaceuticals (USA) Inc. has received tentative approval from the United States Food and Drug Administration (USFDA) to market Sugammadex Injection USP 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL), Single-Dose Vial (US RLD: Bridion®).

Sugammadex is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery. The drug will be manufactured at the group's injectables manufacturing facility at Jarod, India.

Sugammadex Injection had annual sales of USD 772 mn in the United States according to IQVIA MAT July 2022.

The group now has 323 approvals and has so far filed over 428* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th June 2022)*

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PRESS RELEASE

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