Zydus receives Tentative Approval from the USFDA for Edaravone Injection, 30 mg/100 mL (0.3 mg/mL), Single-Dose Vial

Ahmedabad, India, March 14, 2024

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as "Zydus") has received tentative approval from the United States Food and Drug Administration (USFDA) to manufacture and market Edaravone Injection, 30 mg/100 mL (0.3 mg/mL), Single-Dose Vial, (RLD: RADICAVA®).

Edaravone is used to treat a certain type of nerve disease called amyotrophic lateral sclerosis (ALS, also commonly called Lou Gehrig's disease). The drug will be manufactured at the group's injectable manufacturing facility at Jarod, near Vadodara (India).

Edaravone Injection, 30 mg/100 mL (0.3 mg/mL), had annual sales of USD 19 mn. in the United States (IQVIA MAT Jan-24).

The group now has 390 approvals and has so far filed over 460* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2023)

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PRESS RELEASE

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