Zydus receives Final Approval from the USFDA for Chlorpromazine Hydrochloride Injection USP, 25 mg/mL and 50 mg/2 mL (25 mg/mL), Single-Dose Vials

Ahmedabad, India, March 14, 2024

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 Chlorpromazine Hydrochloride Injection USP, 25 mg/mL and 50 mg/2 mL (25 mg/mL), Single-Dose Vials, (RLD: Thorazine Injection).

Chlorpromazine Hydrochloride Injection is used to treat certain mental/mood disorders (such as schizophrenia, psychotic disorders, manic phase of bipolar disorder, severe behavioral problems in children). It is also used to control nausea/vomiting, relieve prolonged hiccups, relieve restlessness/anxiety before surgery, treat a certain liver problem (porphyria), and help treat tetanus. The drug will be manufactured at the group's injectable manufacturing facility at Jarod, near Vadodara (India).

Chlorpromazine Hydrochloride Injection USP, 25 mg/mL and 50 mg/2 mL (25 mg/mL), Single-Dose Vials, had annual sales of USD 12.5 mn. in the United States (IQVIA MAT Jan-24).

The group now has 391 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)

###

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)
Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878