Zydus receives final approval from the USFDA for Famotidine Injection

Ahmedabad, India, 23 November, 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 Famotidine Injection USP, 40 mg/4 mL (10 mg/mL) and 200 mg/20 mL (10 mg/mL) multiple-dose vials (USRLD: Pepcid® injection).

Famotidine Injection is indicated to treat ulcers of the stomach and intestines and to prevent intestinal ulcers from coming back after they have healed. This medication is also used to treat certain stomach and throat (esophagus) problems such as erosive esophagitis, gastroesophageal reflux disease-GERD and Zollinger-Ellison syndrome.

Famotidine Injection had annual sales of USD 1.9 mn in the United States according to IQVIA data (IQVIA MAT Sep 2022). The drug will be manufactured at the group's injectable manufacturing facility at Jarod, near Vadodara, India.

The group now has 333 approvals and has so far filed over 431* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th September 2022)*

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PRESS RELEASE

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