Zydus receives final approval from the USFDA for Acetaminophen injection

Ahmedabad, India, 29 October, 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 Acetaminophen Injection, 1,000 mg/100 mL (10 mg/mL) single-dose vials (USRLD: Ofirmev®).

Acetaminophen injection is indicated to relieve mild to moderate pain and to reduce fever. It is also used in combination with opioid (narcotic) medications to relieve moderate to severe pain. The drug will be manufactured at the group's injectable manufacturing facility at Jarod, near Vadodara, India.

Acetaminophen injection had annual sales of USD 72 mn in the United States according to IQVIA data (IQVIA MAT Aug 2022).

The group now has 330 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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