Zydus receives tentative approval from the USFDA for Levothyroxine Sodium for Injection

Ahmedabad, India, 28 November, 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 Levothyroxine Sodium for injection, 100 mcg/vial, 200 mcg/vial, and 500 mcg/vial (USRLD: Levothyroxine Sodium injection manufactured by Fresenius Kabi USA, LLC).

Levothyroxine Sodium injection is indicated for the treatment of myxedema coma. The drug will be manufactured at the group's injectable manufacturing facility at Jarod, near Vadodara, India.

Levothyroxine Sodium injection had annual sales of USD 45.2 mn in the United States according to IQVIA data (IQVIA MAT Sep 2022).

The group now has 334 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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