Zydus receives final approval from the USFDA for Empagliflozin and Metformin Hydrochloride Tablets

Ahmedabad, India, 11 July, 2022

Zydus Lifesciences Ltd. (formerly known as Cadila Healthcare Ltd.), has received final approval from the United States Food and Drug Administration (USFDA) to market Empagliflozin and Metformin Hydrochloride Tablets in the strengths of 5 mg/500 mg, 5 mg/1000 mg, 12.5 mg/500 mg, and 12.5 mg/1000 mg (US RLD: Synjardy®).

Empagliflozin and Metformin Hydrochloride tablets are used with proper diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. They are also used to lower the risk of cardiovascular death in patients with type 2 diabetes mellitus and established cardiovascular disease. The drug will be manufactured at the group's formulation facility at SEZ, Ahmedabad, India.

Synjardy® (Empagliflozin and Metformin Hydrochloride) tablets had annual sales of 281 million in the United States according to IQVIA data (IQVIA MAT May 2022).

The group now has 316 approvals and has so far filed over 420* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 31st March 2022)*

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PRESS RELEASE

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