Press Release

Zydus Cadila receives tentative approval from USFDA for Dapagliflozin Tablets

Ahmedabad, 29 October, 2020

Zydus Cadila has received tentative approval from the USFDA to market Dapagliflozin Tablets, 5 mg and 10 mg (US RLD: Farxiga® Tablets). Dapagliflozin is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.

Zydus Cadila is believed to be the only company with tentative approval that has submitted a paragraph IV certification for US Patent No. 6,515,117 that claims the Dapagliflozin compound. The US District Court for the District of Delaware has scheduled a trial in February 2021 regarding Zydus Cadila's patent challenge.

The drug will be manufactured at the group's formulation manufacturing facility at the SEZ, Ahmedabad.

The group now has 311 approvals and has so far filed over 390 ANDAs since the commencement of the filing process in FY 2003-04.

About Zydus Cadila
Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs nearly 25000 people worldwide and is dedicated to creating healthier communities globally.

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