Press Release

Zydus receives final approval from USFDA for Dapagliflozin Tablets

Ahmedabad, India, 23 February, 2022

Zydus has received final approval from the USFDA to market Dapagliflozin Tablets in the strengths of 5 mg and 10 mg (USRLD: Farxiga). Dapagliflozin is used with a proper diet and exercise program to control high blood sugar in people with type 2 diabetes. Dapagliflozin also lowers the risk of heart failure in adults with type 2 diabetes with heart disease. It is also used to lower the risk of further worsening of kidney disease, end-stage kidney disease (ESKD), death due to cardiovascular disease, and hospitalization for heart failure in adults with chronic kidney disease. Dapagliflozin works by increasing the removal of sugar by kidneys.

The drug will be manufactured at the group's formulation manufacturing facility at the SEZ, Ahmedabad. The group now has 328 approvals and has so far filed over 400 ANDAs since the commencement of the filing process in FY 2003-04.

About Zydus

The Zydus Group with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 23000 people worldwide and is driven by its mission to unlock new possibilities in life-sciences through quality healthcare solutions that impact lives. The group aspires to become a global life-sciences company transforming lives through pathbreaking discoveries.

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