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AstraZeneca's Dapagliflozin receives approval in India for heart failure treatment

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Dapagliflozin (Forxiga) is the first SGLT-2 inhibitor proven to significantly reduce the risk of Cardiovascular death and hospitalisation for heart failure in patients with HFrEF

AstraZeneca Pharma India Limited (AstraZeneca India), a leading science-led biopharmaceutical company, has received the Marketing Authorization for Dapagliflozin (Forxiga), for the treatment of patients with heart failure with reduced ejection fraction (HFrEF).

This is the first in class SGLT-2 inhibitor drug approved for the treatment of HFrEF and is the first drug proven to significantly reduce the risk of Cardiovascular death and hospitalisation for Heart Failure in patients with HFrEF.

The approval follows positive results from the landmark Phase III DAPA-HF trial, that proved that Dapagliflozin in addition to standard of care, reduced the risk of the composite outcome of Cardiovascular death or the worsening of Heart Failure versus placebo by 26%.

About one-fourth patients in the study population were from Asian region including India.

Gagandeep Singh, Managing Director, AstraZeneca Pharma India Limited said, " Heart Failure is a serious health condition that affects ~6.4 crore people worldwide and at least 8–10 million in India. The accelerated regulatory approval in India will provide the much-needed treatment to help patients reduce their disease burden & live longer".

Dr. Anil Kukreja, Vice President – Medical Affairs & Regulatory, AstraZeneca India said, “Despite currently available therapies for management of Heart failure, significant unmet needs exist globally as well as in India. This approval for Dapaglifozin (Forxiga) based on significant and clinically meaningful results from Dapa-HF trial provides much required confidence on a novel pharmacological approach, first in class SGLT2 inhibitor, for management of patients with HFrEF. This approval is boon for HFrEF patients in India where considerable efforts are required to address significant unmet needs of frequent hospitalization, urgent visits to hospital emergency room and cardiovascular death in HF patients despite available therapies ”

The U.S. Food and Drug Administration approved Dapagliflozin to be used in management of patients with heart failure with reduced ejection fraction. The Canadian Cardiovascular Society has updated their guidelines and recommend the use of SGLT2i drugs like Dapagliflozin to manage heart failure to provide better patient care.

Dapaglifozin (Forxiga) is also indicated as an adjunct to diet and exercise to improve glycaemic control in adults with T2D in India. The drug is also approved for reduction of risk of hospitalisation due to Heart failure in Type 2 Diabetes patients with high risk factors.