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AstraZeneca’s Dapagliflozin gets additional indication approval for heart failure treatment in India

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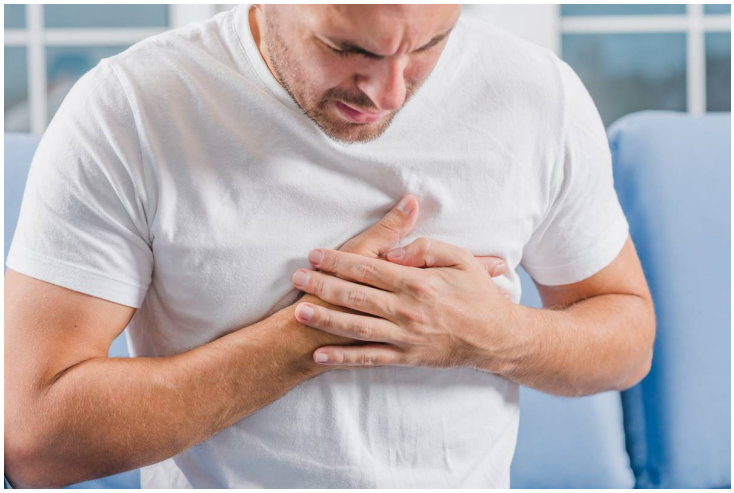
The approval allows treatment of heart failure patients irrespective of the ejection fraction based on new trial DELIVER conducted by AstraZeneca



AstraZeneca Pharma India has received extended indication approval from the Drugs Controller General of India (DCGI) for its drug, Dapagliflozin in the treatment of heart failure (HF) in adults.

The approval is based on the detailed results from the DELIVER Phase III trial—the largest and broadest HF trial to date in patients with LVEF (left ventricular ejection fraction) >40%.

AstraZeneca’s original research product dapagliflozin significantly reduced the composite of cardiovascular (CV) death or worsening heart failure in patients with HF with mildly reduced or preserved ejection fraction (EF), compared to placebo. The results were consistent across pre-defined subgroups.

Dapagliflozin is already approved for HF with reduced ejection fraction. The additional indication will expand the indication for all types of HF irrespective of ejection fraction. Dapagliflozin is the only SGLT-2i which has shown mortality benefits in the pooled analysis of heart failure across LVEF.

Heart failure is a chronic, progressive disease impacting nearly 64 million people globally and about 10 million in India, which comprises of both heart failure with preserved ejection fraction and reduced ejection fraction. The available data from Indian HF registries show that HF patients in India are younger by 10-years, and the majority of the burden lies below 65 years of age, as compared to the patients from high-income countries.

Dapagliflozin is currently being tested in patients without type 2 Diabetes (T2D) following an acute myocardial infarction or heart attack in the DAPA-MI Phase III trial - a first of its kind, indication-seeking registry-based randomised controlled trial.