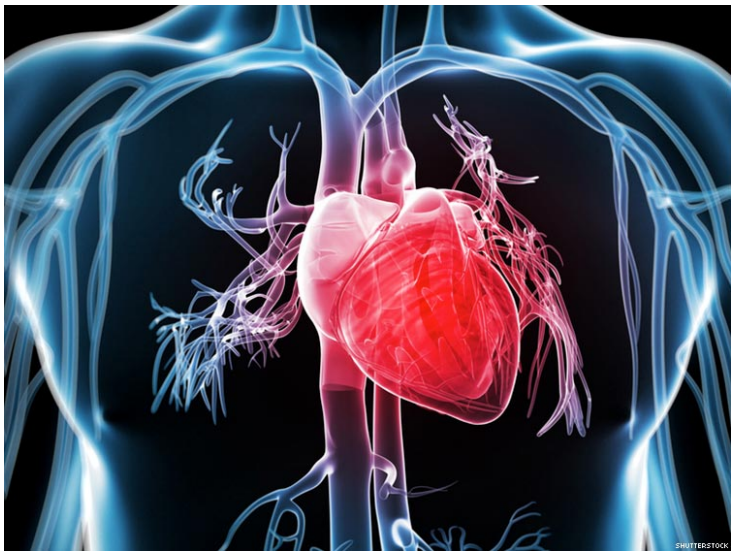
BioSpectrum
the business of Bio & Health Sciences

FDA grants Fast Track designation for Farxiga in heart failure

19 September 2019 | News

The Fast Track designation is based on two Phase III trials, DAPA-HF and DELIVER, which investigated the role of Farxiga in patients with heart failure with reduced ejection fraction (HFrEF) and preserved ejection fraction (HFpEF), respectively



AstraZeneca has announced that the US Food and Drug Administration (FDA) has granted Fast Track designation for the development of Farxiga (dapagliflozin) to reduce the risk of cardiovascular (CV) death, or the worsening of heart failure, in adults with heart failure with reduced ejection fraction (HFrEF) or preserved ejection fraction (HFpEF).

The FDA's Fast Track programme is designed to accelerate the development and review of new medicines for the treatment of serious conditions where there is an unmet treatment need.

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: "Heart failure affects approximately 64 million people worldwide, and about half will die within five years of diagnosis. This Fast Track designation for Farxiga brings us closer to fulfilling our ambition to help prevent, treat and cure heart failure, and we look forward to working with the FDA to explore Farxiga as a potential new treatment option for heart failure patients."

The Fast Track designation is based on two Phase III trials, DAPA-HF and DELIVER, which investigated the role of Farxiga in patients with heart failure with reduced ejection fraction (HFrEF) and preserved ejection fraction (HFpEF), respectively.

Farxiga is currently approved as a monotherapy and as part of combination therapy to improve glycaemic control in adults with type-2 diabetes (T2D). In August 2019 the FDA granted Fast Track designation for the development of Farxiga to delay the progression of renal failure and prevent CV and renal death in patients with chronic kidney disease.