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AstraZeneca's heart failure drug Farxiga gets FDA priority review

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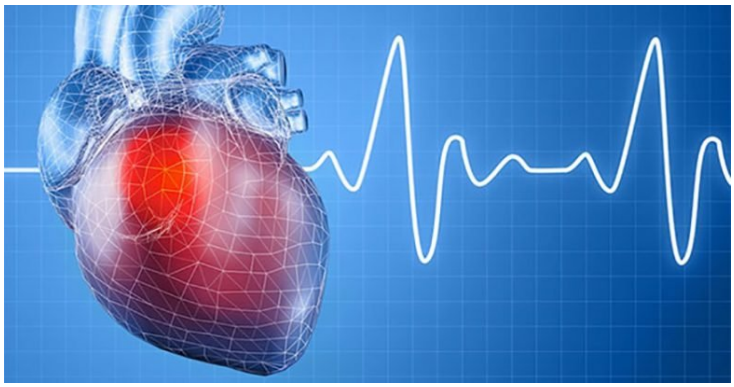
US Food and Drug Administration has accepted a supplemental New Drug Application and granted Priority Review for Farxiga (dapagliflozin) to reduce the risk of cardiovascular (CV) death or the worsening of heart failure (HF) in adults with heart failure with reduced ejection fraction



AstraZeneca has announced the US Food and Drug Administration (FDA) has accepted a supplemental New Drug Application (sNDA) and granted Priority Review for *Farxiga* (dapagliflozin) to reduce the risk of cardiovascular (CV) death or the worsening of heart failure (HF) in adults with heart failure with reduced ejection fraction (HFrEF) with and without type-2 diabetes (T2D). *Farxiga* is a first-in-class, oral once-daily selective inhibitor of human sodium-glucose co-transporter 2 (SGLT2).

The Prescription Drug User Fee Act date, the FDA action date for this supplemental application, is scheduled for the second quarter of 2020.

The sNDA was based on results from the landmark Phase III DAPA-HF trial published in September 2019 in *The New England Journal of Medicine*, which showed *Farxiga* on top of standard of care reduced the incidence of the composite outcome of CV death or the worsening of HF versus placebo.

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: "*Farxiga* is well established in the treatment of type-2 diabetes and this Priority Review shows its potential to also impact millions of patients with heart failure. If approved, *Farxiga* will be the first and only medicine of its kind indicated to treat patients with heart failure."

In September 2019, the FDA granted Fast Track designation for the development of *Farxiga* in HF. In August 2019, the FDA also 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, with and without T2D.

Farxiga is indicated as a monotherapy and as part of combination therapies to improve glycaemic control in adults with T2D. In October 2019, the FDA also approved *Farxiga* to reduce the risk of hospitalisation for heart failure in patients with T2D and established cardiovascular disease or multiple CV risk factors.