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AstraZeneca’s diabetes drug gets USFDA nod to ease heart failure risk

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The approval is based on results from the landmark DECLARE-TIMI 58 CV outcomes trial (CVOT)

AstraZeneca has announced that the US Food and Drug Administration (FDA) has approved *Farxiga* (dapagliflozin) to reduce the risk of hospitalisation for heart failure (hHF) in adults with type-2 diabetes (T2D) and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.

The approval is based on results from the landmark DECLARE-TIMI 58 CV outcomes trial (CVOT), the largest sodium-glucose cotransporter 2 (SGLT2) inhibitor CVOT conducted to date to evaluate T2D patients with multiple CV risk factors or established CV disease.

Today’s US FDA approval follows the update to the marketing authorisation in the EU in August 2019. *Farxiga* is also under regulatory review in China with a decision anticipated in the first half of 2020.

The US FDA has granted Fast Track designation for *Farxiga* to reduce the risk of CV death, or the worsening of heart failure in adults with heart failure with reduced ejection fraction (HFrEF) or preserved ejection fraction (HFpEF) based on the Phase III DAPA-HF and DELIVER trials, and Fast Track designation to delay the progression of renal failure and prevent CV and renal death in patients with chronic kidney disease (CKD) based on the Phase III DAPA-CKD trial.