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FDA fast tracks AstraZeneca's FARXIGA

28 August 2019 | News

FDA Grants Fast Track Designation for FARXIGA in Chronic Kidney Disease

AstraZeneca has announced that the US Food and Drug Administration (FDA) has granted Fast Track designation for the development of FARXIGA (dapagliflozin) to delay the progression of renal failure and prevent cardiovascular (CV) and renal death in patients with chronic kidney disease (CKD).

The FDA's Fast Track program is designed to accelerate the development and review of new medicines for the treatment of serious conditions where there is an unmet treatment need. The designation was assigned to CKD patients with and without type 2 diabetes (T2D).

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: "Chronic kidney disease affects an estimated 37 million people in the US, and is often associated with an increased risk of heart disease and stroke. This Fast Track designation is an important step towards more quickly addressing unmet treatment needs in chronic kidney disease, and we will work closely with the FDA to explore the potential for FARXIGA to improve outcomes for these patients."

The Phase III DAPA-CKD clinical trial is currently underway to evaluate the effect of FARXIGA on renal outcomes and CV mortality in patients with CKD with and without T2D versus placebo, on top of standard of care.