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AstraZeneca India's anti-diabetic drug receives approval for CKD treatment

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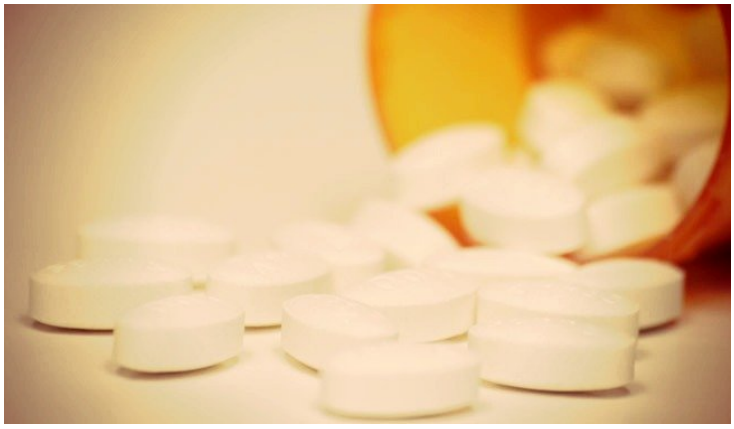
AstraZeneca’s dapagliflozin is the first medicine in SGLT-2i class to move into a new disease area by demonstrating efficacy and safety data for the treatment of patients with chronic kidney disease (CKD)



AstraZeneca India (AstraZeneca Pharma India Limited), a leading science-led biopharmaceutical company, announced that they have received marketing authorisation for their anti-diabetic drug dapagliflozin, in India for the treatment of patients of chronic kidney disease (CKD) up to Stage III. The receipt of this permission paves way for the launch of Dapagliflozin Tablets 10mg into a new disease area to nephrologists in India.

AstraZeneca’s dapagliflozin is the first medicine in SGLT-2i class to move into a new disease area by demonstrating efficacy and safety data for the treatment of patients with chronic kidney disease (CKD). The study results of dapagliflozin, showed significant benefits in reducing CKD progression in patients with and without type-2 diabetes. The DAPA-CKD study concluded globally on March 30, 2020 based on its effectiveness and safety.

Dr Anil Kukreja, Vice President – Medical Affairs & Regulatory, AstraZeneca India said “With the approval of dapagliflozin for CKD in India, an already effective type 2 diabetes and select heart failure treatment, can now be used by nephrologists in the management of chronic kidney disease.”

Dr Dinesh Khullar, National Lead Investigator, Dapa-CKD, India, said, “This will go a long way in the effective clinical management of diabetes and its complications in India. Its Approval by the regulatory bodies in India is a welcome move and will benefit CKD patients, both diabetics and non diabetics, including those where the disease has already progressed significantly.”

In May 2020, dapagliflozin was approved by US FDA to reduce the risk of CV death and hospitalisation for heart failure (hHF) in adults with heart failure (NYHA class II-IV) with reduced ejection fraction (HFrEF) with and without T2D.