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AstraZeneca's Forxiga approved in Japan for chronic heart failure

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Forxiga is the first SGLT2 inhibitor approved in Japan for chronic heart failure with reduced ejection fraction inadult patients with and without type-2 diabetes

AstraZeneca's *Forxiga* (dapagliflozin) has been approved in Japan for the treatment of patients with chronic heart failure (HF) who are receiving standard of care.

The approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) was based on positive results from the landmark DAPA-HF Phase III trial published in *The New England Journal of Medicine*.[7]

Forxiga is the first sodium-glucose co-transporter 2 (SGLT2) inhibitor to have shown a statistically significant reduction in the risk of the composite of cardiovascular (CV) death or worsening of HF events, including hospitalisation for HF (hHF). The DAPA-HF Phase III trial demonstrated that *Forxiga*, in addition to standard of care, reduced the risk of the composite outcome versus placebo by 26% and both components of the primary composite endpoint contributed benefit to the overall effect.

In the DAPA-HF Phase III trial, the safety profile of *Forxiga* was consistent with the well-established safety profile of the medicine. During the trial, one CV death or hHF or an urgent visit resulting in intravenous therapy associated with HF could be avoided for every 21 patients treated.

Forxiga (known as *Farxiga* in the US) is approved in the US, Europe, and several other countries around the world for the treatment of patients with HF with reduced ejection fraction (HFrEF).

Forxiga is advancing cardiorenal prevention as science continues to identify the underlying links between the heart, kidneys and pancreas. DAPA-HF is part of DapaCare, a robust clinical trial programme to assess the potential CV and renal benefits of *Forxiga*. The programme has also explored the treatment of patients with chronic kidney disease (CKD) in the ground-breaking DAPA-CKD Phase III trial. Additionally, *Forxiga* is currently being tested for HF patients with preserved ejection fraction (HFpEF) in the DELIVER Phase III trial with data readout anticipated in the second half of 2021.

In 2013, AstraZeneca K.K. (AZKK), a subsidiary in Japan of AstraZeneca, entered into an agreement with Ono Pharmaceutical for *Forxiga*. Based on this agreement, Ono is responsible for distribution and marketing of *Forxiga* tablets in Japan and has been co-promoting it with AZKK for the treatment of T2D and type-1 diabetes. Both companies will co-

promote for the treatment of chronic heart failure.