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AstraZeneca submits sNDA for Forxiga in Japan

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Forxiga is also under regulatory review in Europe for use as an oral adjunct treatment to insulin in adults with T1D



Global drug giant, AstraZeneca has submitted a supplemental new drug application (sNDA) to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for the use of Forxiga (dapagliflozin), a selective sodium-glucose co-transporter 2 (SGLT2) inhibitor, as an oral adjunct treatment to insulin in adults with type-1 diabetes (T1D).

Forxiga is also under regulatory review in Europe for use as an oral adjunct treatment to insulin in adults with T1D.

The Japan sNDA is based on Phase III data from the DEPICT (Dapagliflozin Evaluation in Patients with Inadequately Controlled Type 1 Diabetes) clinical programme for *Forxiga* in T1D and a dedicated trial in Japanese patients (trial D1695C00001). Results showed that *Forxiga*, when given as an oral adjunct to adjustable insulin in patients with inadequately-controlled T1D, demonstrated significant and clinically-meaningful reductions from baseline in HbA1c, weight and total daily insulin dose at 24 and 52 weeks, compared to placebo, at both 5mg and 10mg doses.

Forxiga is a first-in-class selective inhibitor of human SGLT2 indicated as both monotherapy and as part of combination therapy to improve glycaemic control. Although not indicated for these uses, *Forxiga* provides the added benefits of blood pressure reductions and weight loss in adult patients with type-2 diabetes (T2D).