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AstraZeneca receives DCGI approval for type 2 diabetes drug

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QTERN® combines two anti-hyperglycaemic agents with complementary mechanisms of action in a once-daily tablet

AstraZeneca Pharma India Limited (AstraZeneca India) announced that it has received Import & Market permission for QTERN® (Fixed dose combination of Dapagliflozin 10mg + Saxagliptin 5mg) in India by the Drug Controller General of India (DCGI). This permission paves way for the launch of QTERN® in India, subject to the receipt of further related statutory approvals and licenses.

QTERN® is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus (T2DM). QTERN® combines two anti-hyperglycaemic agents with complementary mechanisms of action in a once-daily tablet. The drug comprises sodium-glucose cotransporter 2 (SGLT2) inhibitor- dapagliflozin and a dipeptidyl peptidase-4 (DPP-4) inhibitor saxagliptin.

SGLT-2 inhibitors help patients achieve improved glycaemic control by reducing the reabsorption of glucose from the blood and enabling its removal via the urine. SGLT-2 inhibitors, including Forxiga (dapagliflozin), have demonstrated reductions in HbA1c and have also been shown to reduce weight and blood pressure. DPP-4 inhibitors reduce blood glucose as measured by HbA1c.

Type 2 diabetes in India is a disease of epidemic scale affecting over 63 million people. Rapid urbanization, industrialization and demographic transition resulting in altered lifestyles have been identified as the main causes for this alarming number. Significant unmet needs still exist, as many patients remain inadequately controlled on their current glucose-lowering regimen. QTERN® will provide yet another option to physicians to help them in managing type 2 diabetes of their patients.

Gagandeep Singh Bedi, Managing Director, AstraZeneca India said, “Type-2 diabetes is a complex disease that is at epidemic proportions, affecting more than 63 million people in India. The approval of QTERN® is good news for patients who may benefit from improved glycaemic control by adding a DPP-4 inhibitor to a SGLT-2 inhibitor in a convenient once-daily tablet”