QTERN (saxa/dapa) EU approved for type-2 diabetes

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ASTRAZENECA RECEIVES APPROVAL IN THE EU FOR *QTERN* (SAXAGLIPTIN AND DAPAGLIFLOZIN) FOR TREATMENT OF TYPE 2 DIABETES

AstraZeneca today announced that the European Commission (EC) has approved *Qtern* (saxagliptin/dapagliflozin) tablets for the treatment of type 2 diabetes in all 28 EU member countries plus Iceland, Liechtenstein and Norway. The fixed-dose combination of saxagliptin and dapagliflozin is the first DPP-4i/SGLT-2i combination product to be approved in Europe.

Qtern is indicated for adults with type 2 diabetes aged 18 years and older to improve glycaemic control when metformin and/or sulphonylurea and one of the mono-components of *Qtern* alone do not provide adequate control, or when a patient is already being treated with the free combination of saxagliptin and dapagliflozin.

Elisabeth Björk, Vice President, Head of Cardiovascular and Metabolic Diseases, Global Medicines Development at AstraZeneca said: "Nearly half of all people with type 2 diabetes are unable to reach their treatment goal and so risk developing complications due to hyperglycaemia. *Qtern* is the first combination product of its kind approved in Europe and an important new treatment option to help patients reach their goals through powerful HbA1c reduction."

The approval is based on data from three trials in type 2 diabetes submitted to the European Medicines Agency. In two trials, the combination of saxagliptin and dapagliflozin with metformin resulted in statistically significant reductions in HbA1c in comparison to patients treated with placebo. An additional trial showed that the combination of saxagliptin and dapagliflozin added to metformin resulted in statistically superior reductions in HbA1c in comparison to patients treated with saxagliptin or dapagliflozin alone added to metformin. In these trials, the safety profile of *Qtern* was similar to the known safety profiles of saxagliptin and dapagliflozin.

About AstraZeneca in Diabetes

AstraZeneca is pushing the boundaries of science with the goal of developing life-changing medicines that aim to reduce the global burden and complications of diabetes. Our current portfolio consists of the three newest classes of non-insulin, anti-diabetic treatments that support individualised treatment approaches: SGLT-2 inhibitors, GLP-1 receptor agonists and DPP-4 inhibitors.

As a main therapy area for the company, we are focusing our research and development efforts on diverse populations and patients with significant co-morbidities, such as cardiovascular disease, obesity, non-alcoholic steatohepatitis (NASH) and chronic kidney disease.

Our commitment to diabetes is exemplified by the depth and breadth of our global clinical research programme. This commitment is advancing understanding of the treatment effects of our diabetes medicines in broad patient populations, as well as exploring combination product approaches to help more patients achieve treatment success earlier in their disease progression. Our ambition is to reduce the long-term impact of diabetes.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Respiratory and Autoimmunity, Cardiovascular and Metabolic Diseases, and Oncology. The Company is also active in inflammation, infection and neuroscience through numerous collaborations. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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