POSITIVE CHMP OPINION IN EU FOR SAXA/DAPA (SAXAGLIPTIN AND DAPAGLIFLOZIN) FOR ADULTS WITH TYPE-2 DIABETES

AstraZeneca today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has issued a positive opinion, recommending the approval of saxa/dapa (saxagliptin and dapagliflozin) tablets for the treatment of adults with type-2 diabetes. The fixed-dose combination of saxagliptin and dapagliflozin has the potential to be the first DPP-4i/SGLT-2i combination product approved in Europe.

Saxa/dapa is a fixed-dose combination of saxagliptin and dapagliflozin being developed as a treatment for patients with type-2 diabetes in adults aged 18 years and older. It is recommended to be indicated as a treatment to improve glycaemic control when metformin and/or sulphonylurea and one of the mono-components of saxa/dapa alone do not provide adequate glycaemic control, or when a patient is already being treated with the free combination of saxagliptin and dapagliflozin.

The submission included data from three studies in type-2 diabetes. In two studies, the combination of dapagliflozin and saxagliptin with metformin resulted in statistically significant reductions in HbA1c in comparison to patients treated with placebo that required additional control to existing saxagliptin and metformin or dapagliflozin and metformin therapy. An additional study showed that the combination of dapagliflozin and saxagliptin added on to metformin resulted in statistically superior reductions in HbA1c in comparison to patients treated with dapagliflozin or saxagliptin alone added to metformin. In these trials, the safety profile of saxa/dapa was similar to the known safety profiles of saxagliptin and dapagliflozin.

The CHMP's positive opinion will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU). The final decision by the EC is expected in the coming months, and will be applicable to all 28 EU member countries plus Iceland, Norway and Liechtenstein.

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 strategic 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 treatment 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, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune

disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

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