

AstraZeneca Receives Complete Response Letter from US FDA for SaxaGLIPTIN / dapaGLIFLOZIN Fixed-Dose-Combination

[AstraZeneca](#) today announced that the US Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for the investigational fixed-dose combination of saxagliptin and dapagliflozin for the treatment of adult patients with type 2 diabetes.

The CRL states that more clinical data are required to support the application. This includes clinical trial data from ongoing or completed studies and may require information from new studies. AstraZeneca will work closely with the FDA to determine the appropriate next steps for the NDA and remains committed to the development of the saxagliptin/ dapagliflozin fixed-dose combination.

This announcement does not affect ongoing interactions with other health authorities as part of these individual application procedures. Based on the information available, the CRL is not expected to affect individual components of saxagliptin or dapagliflozin, which are approved for the treatment of adult patients with type 2 diabetes.

About Type 2 Diabetes

Diabetes is estimated to affect 29.1 million people in the US and more than 387 million people worldwide. The prevalence of diabetes is projected to reach more than 592 million people worldwide by 2035 and type 2 diabetes accounts for approximately 90-95 percent of all diagnosed cases in the US. Type 2 diabetes is a chronic and progressive disease characterised by multiple pathophysiologic defects leading to elevated glucose levels. Significant unmet needs still exist, as many patients remain inadequately controlled on their current glucose-lowering regimen. It is estimated that nearly half of people living with type 2 diabetes are not achieving recommended HbA1c goals based on guidelines established by professional societies and advocacy organizations for diabetes management.

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, heart failure, 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 DPP-4 Inhibition

Incretin hormones are released into the bloodstream in response to meals and increase insulin release in a glucose-dependent manner but are inactivated by the DPP-4 enzyme within minutes. DPP-4 inhibitors slow the inactivation of the incretin hormones, thereby reducing fasting and postprandial glucose concentrations in a glucose-dependent manner.

About SGLT-2 Inhibition

The kidney plays a contributing role in maintaining normal glucose balance, in part by filtering and subsequently reabsorbing glucose back into circulation. SGLT-2, a sodium-glucose cotransporter found predominantly in the kidney, is responsible for the majority of glucose reabsorption. Selective inhibition of SGLT-2 reduces the reabsorption of glucose and lowers the renal threshold for glucose thereby enabling its removal via the urine.

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 cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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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