25 January 2018
EMA/CHMP/12848/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Steglujan

ertugliflozin / sitagliptin

On 25 January 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Steglujan, intended for the treatment of type 2 diabetes. The applicant for this medicinal product is Merck Sharp & Dohme Limited.

Steglujan is a fixed dose combination of ertugliflozin and sitagliptin, two oral blood glucose lowering medicines (ATC code: A10BD24). It will be available as film-coated tablets (containing either 5 mg ertugliflozin and 100 mg sitagliptin, or 15 mg ertugliflozin and 100 mg sitagliptin). Ertugliflozin works by blocking a protein in the kidney called the human sodium-glucose co-transporter-2 (SGLT2). This reduces glucose re-absorption in the kidney leading to glucose excretion in the urine. Sitagliptin is a dipeptidyl peptidase 4 (DPP-4) inhibitor. DPP-4 inhibition reduces the cleavage and inactivation of the incretin hormone glucagon-like peptide 1 (GLP-1), leading to an increase in incretin levels, which in turn stimulates glucose-dependent insulin secretion and inhibits the release of glucagon.

The benefit with Steglujan is its ability to lower blood glucose. The most common side effects are vulvovaginal mycotic infection and other female genital mycotic infections. Serious diabetic ketoacidosis occurs rarely.

The full indication is:

"Steglujan is indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:

- when metformin and/or a sulphonylurea (SU) and one of the monocomponents of Steglujan do not provide adequate glycaemic control;
- in patients already being treated with the combination of ertugliflozin and sitagliptin as separate tablets.

(For study results with respect to combinations and effects on glycaemic control, see sections 4.4, 4.5, and 5.1.)"

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.