15 September 2016
EMA/CHMP/595813/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Glyxambi

empagliflozin / linagliptin

On 15 September 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Glyxambi, intended for the treatment of type 2 diabetes mellitus. The applicant for this medicinal product is Boehringer Ingelheim International GmbH.

Glyxambi is a fixed-dose combination of empagliflozin and linagliptin, two oral blood glucose lowering medicines (ATC code: A10BD19). It will be available as film-coated tablets (containing either 10 mg empagliflozin and 5 mg linagliptin, or 25 mg empagliflozin and 5 mg linagliptin). Empagliflozin is a competitive, reversible, selective and orally active inhibitor of the human sodium-glucose co-transporter 2 (SGLT2) which reduces renal glucose re-absorption leading to urinary glucose excretion. Linagliptin 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 Glyxambi is its ability to lower blood glucose. The most common side effect was urinary tract infection (7.5% with Glyxambi 10 mg/5 mg and 8.5% with Glyxambi 25 mg/5 mg). The most serious adverse reactions were ketoacidosis (<0.1%), pancreatitis (0.2%), hypersensitivity (0.6%), and hypoglycaemia (2.4%).

The full indication is:

“Glyxambi, fixed dose combination of empagliflozin and linagliptin, is indicated in adults aged 18 years and older with type 2 diabetes mellitus:

- to improve glycaemic control when metformin and/or sulphonylurea (SU) and one of the monocomponents of Glyxambi do not provide adequate glycaemic control
- when already being treated with the free combination of empagliflozin and linagliptin”

Detailed recommendations for the use of this product will be described in the summary of product

[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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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.