15 November 2012
EMA/CHMP/706420/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lyxumia

lixisenatide

On 15 November 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lyxumia, 10 µg, 20 µg and 10 µg/20 µg, solution for injection, intended for the treatment of type 2 diabetes. The applicant for this medicinal product is sanofi-aventis groupe. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Lyxumia is lixisenatide, a Glucagon-like peptide 1 (GLP-1) analogue medicinal product. Like native GLP-1, lixisenatide stimulates insulin release from the pancreatic islets, suppresses glucagon secretion, delays gastric emptying, and reduces body weight.

The main benefit of Lyxumia is its ability to improve glucose metabolism when added to an existing oral antidiabetic therapy and/or insulin as advised in the summary of product characteristics (SmPC). An additional benefit is the associated loss in body weight in most combinations.

The most common side effects are nausea, vomiting and diarrhoea. In addition, hypoglycaemia (when Lyxumia was used in combination with a sulphonylurea and/or a basal insulin) and headache occurred commonly. Allergic reactions have been reported in 0.4% of Lyxumia patients.

Specific safety issues regarding the potential risks of medullary thyroid cancer, pancreatitis, malignant neoplasms, a propensity to induce a transient increased heart rate, and malformations observed in animal development studies have been evaluated and are addressed in the SmPC and/or in the Risk Management Plan.

A pharmacovigilance plan for Lyxumia will be implemented as part of the marketing authorisation.

The approved indication is: "Treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these,

[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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together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4 and 5.1 for available data on the different combinations)."

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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Lyxumia and therefore recommends the granting of the marketing authorisation.