20 February 2014
EMA/CHMP/90545/2014 – Corr(*)
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vokanamet

Canagliflozin/metformin

On 20 February 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vokanamet, 50mg/850mg, 50mg/1000mg, 150mg/850 mg and 150mg/1000mg, film-coated tablets intended for the treatment type 2 diabetes mellitus.

The applicant for this medicinal product is Janssen-Cilag International N.V. 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 substances of Vokanamet are canagliflozin and metformin, blood glucose-lowering agents, ATC code: A10BD16. Vokanamet combines two compounds, which have different modes of action. Canagliflozin 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, thereby lowering levels of glucose in the blood of patients with type 2 diabetes. Metformin works by suppressing glucose production by the liver.

The benefits with Vokanamet are its ability to improve glycaemic control. Canagliflozin added to metformin has been shown to confer an additional clinically relevant improvement in glycaemic control, thus justifying the combination of these substances.

The most common side effects of metformin are gastrointestinal symptoms such as nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. The most common side effects of canagliflozin are hypoglycaemia (when used in combination with insulin or a sulphonylurea), vulvovaginal candidiasis, urinary tract infection, and polyuria or pollakiuria.

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

The approved indication is: " treatment of adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

- in patients not adequately controlled on their maximally tolerated doses of metformin alone
- in patients on their maximally tolerated doses of metformin along with other glucose-lowering medicinal products including insulin, when these do not provide adequate glycaemic control
- in patients already being treated with the combination of canagliflozin and metformin as separate tablets."

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 Vokanamet and therefore recommends the granting of the marketing authorisation.

(*) The correction concerns the deletion of the following sentence “It is proposed that Vokanamet be prescribed by physicians experienced in the treatment of type 2 diabetes”.