25 July 2013
EMA/CHMP/229786/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vipidia

alogliptin

On 25 July 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for Vipidia, 6.25 mg, 12.5 mg and 25 mg, film-coated tablet intended for the treatment of type 2 diabetes mellitus. The applicant for this medicinal product is Takeda Pharma A/S. 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 Vipidia is alogliptin, a dipeptidyl peptidase 4 (DPP 4) inhibitor and oral blood glucose-lowering product (ATC Code A10BH04). DPP-4 inhibition reduces the cleavage and inactivation of the active (intact) form of the incretin hormones glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), producing an elevation of incretin concentrations that leads to an enhancement of glucose-dependent insulin secretion and a reduction in glucagon release.

The benefit of Vipidia is its clinically relevant effect on glycaemic control in patients with type 2 diabetes when used in combination with other glucose-lowering medicinal products including insulin. The most common side effects are upper respiratory tract infections, nasopharyngitis, headache, abdominal pain, gastroesophageal reflux disease, pruritus and rash.

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

The approved indication is: "Vipidia is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on 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.

[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 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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