EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 July 2013
EMA/CHMP/223982/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vipdomet
alogliptin / metformin

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 the medicinal product Vipdomet, 12.5 mg / 1000 mg and 12.5 mg / 850 mg, film-coated tablet intended for the treatment of type 2 diabetes mellitus in adults. 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 substances of Vipdomet are alogliptin/metformin, a combination of two oral blood glucose-lowering products (ATC code: A10BD13).

Alogliptin is a dipeptidyl peptidase 4 (DPP 4) inhibitor which 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.

Metformin is a biguanide with antihyperglycaemic effects, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and, therefore, does not produce hypoglycaemia. It is thought to act via various mechanisms, including decreasing hepatic glucose production, decreasing intestinal absorption of glucose, and improving insulin sensitivity by increasing peripheral glucose uptake and utilisation.

Vipdomet combines these two glucose-lowering agents with complementary and distinct mechanisms of action.

The benefit of Vipdomet is its ability to improve the glycaemic control through reduction of blood glucose levels in patients inadequately controlled by metformin alone. The most common side effects reported with combination treatment were nasopharyngitis, upper respiratory tract infection, , , headache, gastroenteritis, abdominal pain, diarrhoea, vomiting, gastritis, gastroesophageal reflux disease, pruritus and rash.

[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

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

The approved indication is:

“Vipdomet is indicated in the treatment of adult patients aged 18 years and older with type 2 diabetes mellitus:

- as an adjunct to diet and exercise to improve glycaemic control in adult patients, inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of alogliptin and metformin.
- in combination with pioglitazone (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and pioglitazone.
- in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control.”

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 Vipdomet and therefore recommends the granting of the marketing authorisation.