European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 25 September 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
JALRA

International Nonproprietary Name (INN): ***vildagliptin***

On 25 September 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Jalra 50 mg tablets intended for treatment of type 2 diabetes mellitus. The applicant for this medicinal product is Novartis Europharm Ltd.

The active substance of Jalra is vildagliptin, a dipeptidyl peptidase 4 (DPP-4) inhibitors medicinal product (A10BH02). DPP-4 inhibition reduces the cleavage and inactivation of the active (intact) form of the incretin hormones, including GLP-1 (glucagon-like peptide 1) and GIP (glucose-dependent insulinotropic polypeptide), producing an elevation of incretin concentrations that lead to enhancement of glucose-dependent insulin secretion and a reduction in glucagon release, thus contributing to the maintenance of glucose homeostasis.
The benefits with Jalra in combination therapy with metformin, a sulphonylurea or a thiazolidinedione are clinically relevant as Jalra induces significant reductions of HbA1c and FPG compared to placebo. Jalra treatment is largely lipid and weight neutral in combination with metformin or a sulphonylurea. The most common side effects when taking Jalra with metformin are tremor, headache, dizziness, nausea and hypoglycaemia. When taking Jalra with a sulphonylurea, they are tremor, headache, dizziness, asthenia and hypoglycaemia. When taking Jalra with a thiazolidinedione, they are weight increase, peripheral oedema.

A pharmacovigilance plan for Jalra, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is:

Treatment of type 2 diabetes mellitus as dual oral therapy in combination with:

- metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin,
- a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance,
- a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data of the reference product Galvus, considers that there is a favourable benefit-risk balance for Jalra and therefore recommends the granting of the marketing authorisation.