European Medicines Agency
Evaluation of Medicines for Human Use

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ASSESSMENT REPORT

FOR

Jalra

International Nonproprietary Name: vildagliptin

Procedure No. EMEA/H/C/001048

Assessment Report as adopted by the CHMP with
all information of a commercially confidential nature deleted.

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1. BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Novartis Europharm Ltd. submitted on 4 July 2008 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Jalra, through the centralised procedure according to Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 24 April 2008.

The legal basis for this application refers to Article 10c of Directive 2001/83/EC, as amended – relating to informed consent from the marketing authorisation holder Novartis Europharm Ltd. for the authorised medicinal product Galvus (EU/1/07/414/001-010 and EU/1/07/414/018).

Licensing status:
The initial product, Galvus, has been given a Community Marketing Authorisation on 26 September 2007.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:

Rapporteur: Bengt Ljungberg Co-Rapporteur: Pierre Demolis

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 4 July 2008.
- The procedure started on 27 July 2008.
- The Rapporteur's Assessment Report was circulated to all CHMP members on 29 August 2008. The Co-Rapporteur's Assessment Report was circulated to all CHMP members on 29 August 2008.
- During the meeting on 22-25 September 2008, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Jalra on 25 September 2008. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 24 September 2008.

2. SCIENTIFIC DISCUSSION

2.1 Introduction

This application has been submitted as an informed consent application in accordance with Article 10c of Directive 2001/83/EC as amended.
Therefore, consent from the MAH of the Galvus application, which had been submitted as a full application under Art 8(3) of Directive 2001/83/EC as amended, has been given allowing access to Module 2 to Module 5 of the initial dossier of this authorised product and any subsequent post-marketing procedures submitted, assessed and approved. The application for Jalra consists only of Module 1 information.

As a consequence, quality, safety and efficacy of the Jalra medicinal product are identical to the up-to-date quality, safety and efficacy profile of Galvus. Information on the scientific discussions can be found in the Galvus CHMP assessment report and in the European Public Assessment Report (EPAR).

The approved indication is:

"Vildagliptin is indicated in the 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."

The recommended dose is 100 mg daily administered as one dose of 50 mg in the morning and one dose of 50 mg in the evening, except for the combined use with a sulphonylurea, where the recommended dose is 50 mg given in the morning.

Vildagliptin belongs to a new class of oral anti-diabetic drugs and is a selective and reversible inhibitor of Dipeptidyl peptidase 4 (DPP-4), the enzyme which inactivates the incretin hormones, glucagon-like peptide-1 (GLP-1), and glucose-dependent insulinotropic polypeptide (GIP), hormones which significantly contribute to the maintenance of glucose homeostasis.

2.2 Quality aspects

Since this application is an informed consent of the Galvus application, the quality data in support of the Jalra application are identical to the up-to-date quality data of the Galvus dossier which have been assessed and approved (including all post-marketing procedures).

2.3 Non-clinical aspects

Since this application is an informed consent of the Galvus application, the non-clinical data in support of the Jalra application are identical to the up-to-date non-clinical data of the Galvus dossier, which have been assessed and approved (including all post-marketing procedures).

2.4 Clinical aspects

Since this application is an informed consent of the Galvus application, the clinical data in support of the Jalra application are identical to the up-to-date clinical data of the Galvus dossier, which have been assessed and approved (including all post-marketing procedures).

2.5 Pharmacovigilance

Detailed description of the Pharmacovigilance system

The CHMP considered that the Pharmacovigilance system as described by the applicant fulfils the legislative requirements.

Risk Management Plan

The CHMP did not require the MAA to submit a risk management plan because the reference product Galvus does not have additional risk minimisation activities beyond providing guidance in the prescribing information.

2.6 Overall conclusions, risk/benefit assessment and recommendation

Since this application is an informed consent of the Galvus application, the CHMP considered that the risk-benefit balance of Jalra was favourable and therefore recommended the granting of the marketing authorisation for the following indication:

“Vildagliptin is indicated in the 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.”