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

London, 25 June 2009
Doc.Ref. EMEA/CHMP/369490/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
ONGLYZA

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

On 25 June 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Onglyza 5 mg film-coated tablet intended for treatment of type 2 diabetes mellitus.

The applicant for this medicinal product is Bristol-Myers Squibb/AstraZeneca EEIG.

The active substance of Onglyza is saxagliptin, a dipeptidyl peptidase 4 (DPP-4) inhibitor medicinal product (A10BH03). DPP-4 inhibition reduces the cleavage and inactivation of the active (intact) form of the incretin hormone glucagon-like peptide 1 (GLP-1), producing an elevation of incretin concentrations that leads to enhancement of glucose-dependent insulin secretion and a reduction in glucagon release.

The benefits with Onglyza are its demonstrated clinically relevant effect on glycaemic control in type 2 diabetic patients when used in combination with sulphonylurea, with metformin, or with a thiazolidinedione. The most common side effects are upper respiratory infection, urinary tract infection, gastroenteritis, sinusitis, nasopharyngitis (in combination with metformin), headache and vomiting. Incidence of hypoglycaemia was low, but increases when taking Onglyza with a sulfonylurea. Similarly, the incidence of oedema was low but may increase when added to a thiazolidinedione.

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

The approved indication is:

Add-on combination therapy
Onglyza is indicated in adult patients with type 2 diabetes mellitus to improve glycaemic control:

- in combination with metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control;
- in combination with a sulphonylurea, when the sulphonylurea alone, with diet and exercise, does not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate.
- in combination with a thiazolidinedione, when the thiazolidinedione alone with diet and exercise, does not provide adequate glycaemic control in patients for whom use of a thiazolidinedione is considered appropriate.

* 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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Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics 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.

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