European Medicines Agency

Doc. Ref. EMEA/416511/2009
P/138/2009

EUROPEAN MEDICINES AGENCY DECISION

of 15 July 2009

on the granting of a product specific waiver for omacetaxine mepesuccinate (EMEA-000484-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

EUROPEAN MEDICINES AGENCY DECISION

of 15 July 2009

on the granting of a product specific waiver for omacetaxine mepesuccinate (EMEA-000484-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use as amended and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by ChemGenex Europe S.A.S. on 22 December 2008 under Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 May 2009 in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver,

(2) It is therefore appropriate to adopt a Decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A waiver for omacetaxine mepesuccinate, powder for solution for injection, subcutaneous use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 2

This decision is addressed to ChemGenex Europe S.A.S., 1 rue des Quatre Chapeaux, 69002, Lyon, France.

Done at London, 15 July 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

Doc. Ref. EMEA/PDCO/312665/2009
EMEA-000484-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE GRANTING OF A PRODUCT-SPECIFIC WAIVER

Scope of the application

Active substance(s):
Omacetaxine mepesuccinate

Condition(s):
Philadelphia chromosome positive chronic myeloid leukaemia in patients who have the T315I Bcr-Abl kinase domain mutation and who are resistant to prior imatinib therapy.

Pharmaceutical form(s):
Powder for solution for injection

Route(s) of administration:
Subcutaneous use

Name/corporate name of the waiver applicant:
ChemGenex Europe S.A.S.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, ChemGenex Europe S.A.S. submitted to the EMEA on 22 December 2008 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 5 February 2009.

Supplementary information was provided by the applicant on 27 March 2009.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report, to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex.

London, 29 May 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

GROUNDS FOR THE GRANTING OF THE WAIVER

GROUNDS FOR THE GRANTING OF THE WAIVER

- **Condition**

  Philadelphia chromosome positive chronic myeloid leukaemia in patients who have the T315I Bcr-Abl kinase domain mutation and who are resistant to prior imatinib therapy.

  The waiver applies to:

  All subsets of the paediatric population from birth to less than 18 years of age

  for powder for solution for injection for subcutaneous use

  on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.