European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 6 April 2010

on the acceptance of a modification of an agreed Paediatric Investigation Plan for plerixafor (Mozobil) (EMEA-000174-PIP01-07-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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@ema.europa.eu http://www.ema.europa.eu

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty on the Functioning of the European Union,

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 decision P/232/2009 of the European Medicines Agency on 27 November 2009,

Having regard to the application submitted by Genzyme Europe B.V. on 7 December 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 February 2010, in accordance with Article 22 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 of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan.

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an agreed Paediatric Investigation Plan.

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

HAS ADOPTED THIS DECISION:

Article 1

Changes to the agreed Paediatric Investigation Plan for plerixafor (Mozobil), solution for injection, subcutaneous use, intravenous 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, are hereby accepted.

Article 2

This decision is addressed to Genzyme Europe B.V., Gooimeer 10, 1411 DD, Naarden, The Netherlands.

Done at London, 6 April 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 February 2010
EMA/PDCO/70353/2010

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000174-PIP01-07-M02

Scope of the application

Active substance(s):

Plerixafor

Invented name:

Mozobil

Condition(s):

Myelosuppression caused by chemotherapy to treat malignant disorders, which requires an autologous haematopoietic stem cell transplant.

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Genzyme Europe B.V.

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Genzyme Europe B.V submitted to the European Medicines Agency on 7 December 2009 an application for modification of the agreed

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

paediatric investigation plan as set out in the European Medicines Agency's decision P/232/2009 of 27 November 2009. The application for modification proposed changes.

The procedure started on 23 December 2009.

Scope of the modification

Some measures and timelines of the original Opinion have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
    - to agree to the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan.
2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

London, 19 February 2010

On behalf of the Paediatric Committee

Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver

1. Condition(s)

Myelosuppression caused by chemotherapy to treat malignant disorders, which requires an autologous haematopoietic stem cell transplant.

2. Waiver

2.1 Condition

Myelosuppression caused by chemotherapy to treat malignant disorders, which requires an autologous haematopoietic stem cell transplant.

The waiver applies to:

Preterm newborn infants

Term newborn infants from birth to less than 28 days

Infants and toddlers from 28 days to less than 12 months

for solution for injection for subcutaneous and intravenous use

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

3. Paediatric Investigation Plan

3.1 Condition to be investigated

Myelosuppression caused by chemotherapy to treat malignant disorders, which requires an autologous haematopoietic stem cell transplant.

3.2 Indication targeted by the pip

Mobilisation of stem cells into the peripheral blood for harvesting by aphaeresis and subsequent autologous transplantation.

3.3 Subset(s) of the paediatric population concerned by the paediatric development

From 1 to less than 18 years of age.

3.4 Pharmaceutical form(s)

Solution for injection for subcutaneous and intravenous use.

3.5 Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	Study No.1: Juvenile animal development study.
Clinical	2	Study No.2: Combined dose ranging and randomised, open label, comparative study of the efficacy and safety of plerixafor in addition to standard regimens for mobilisation of haematopoietic stem cells into peripheral blood, and subsequent collection by apheresis, versus standard mobilisation regimens alone in paediatric patients, aged 2 to less than 18 years, with solid tumours eligible for autologous transplants. Study No.3: Randomised, comparative study of the efficacy and safety of plerixafor in addition to standard regimens for mobilisation of haematopoietic stem cells into peripheral blood, and subsequent collection by apheresis, versus standard mobilisation regimens alone in paediatric patients, aged 1 to less than 2 years, with solid tumours eligible for autologous transplants. This study may be incorporated into study No.1 above or may be conducted separately.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	By June 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name Name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/09/537/001	Mozobil	20 mg/ml	Solution for injection	Subcutaneous use	vial (glass)	24 mg / 1.2 ml	1 vial