European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 1 December 2008

on the application for agreement of a Paediatric Investigation Plan for maraviroc (CELSENTRI), EMEA-000020-PIP01-07, in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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on the application for agreement of a Paediatric Investigation Plan for maraviroc (CELSENTRI), EMEA-000020-PIP01-07, 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 Pfizer Limited on 27 July 2007 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 October 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 21 of said Regulation**,**

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 a positive opinion.

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a deferral.

[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 Paediatric Investigation Plan for maraviroc (CELSENTRI), film-coated tablets, oral solution, oral 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 agreed.

Article 2

A deferral for maraviroc (CELSENTRI), film-coated tablets, oral solution, oral 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 3

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, CT13 9NJ, United Kingdom.

Done at London, 1 December 2008

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/493720/2008
EMEA-000020-PIP01-07

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Maraviroc

Invented name:
CELSENTRI

Condition(s):
Human immunodeficiency virus infection

Pharmaceutical form(s):
Film-coated tablets
Oral solution

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Pfizer Limited

Information about the authorised medicinal product:
See Annex II.

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Pfizer Limited submitted for agreement to the EMEA on 27 July 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 30 August 2007.

Supplementary information was provided by the applicant on 15 August 2008.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report, by consensus:

- to agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended.

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

2. The measures and timelines of the agreed paediatric investigation plan are set out in the Annex I.

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

London, 17 October 2008

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

A. CONDITION(S) / DISEASE(S)

Human immunodeficiency virus infection

B. WAIVER

Not applicable

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Human immunodeficiency virus infection

- **Proposed PIP indication**

Treatment of human immunodeficiency virus (HIV-1) infection, in combination with other antiretroviral medicinal products, in treatment-experienced children infected with only CCR5-tropic HIV-1 detectable

- **Subset(s) of the paediatric population concerned by the paediatric development**

All subsets of the paediatric population.

- **Formulation(s)**

Film-coated tablet for oral use

Oral solution for oral use

- **Studies**

Area	Number of studies	Description
Quality	1	Development of the film-coated tablet
Quality	1	Development of an age appropriate oral formulation
Clinical	1	Open-label, two-stage, non-comparative, multi-center study to evaluate the safety, tolerability and pharmacokinetics/dosing of multiple doses of maraviroc combined with optimised background therapy (OBT) in antiretroviral (ARV) treatment-experienced children and adolescents from 2 to less than 18 years.
Clinical	1	Open-label, non-randomised, non-comparative, multi-center study to evaluate the safety, tolerability and pharmacokinetics of multiple doses of maraviroc in children infected with CCR5 tropic HIV-1 from birth to less than 2 years of age. The applicant must rediscuss with the PDCO the need for such study as well as the measures and timelines prior to its initiation

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 December 2014**
Deferral for initiation of some or all studies contained in the paediatric investigation plan:	**Yes**
Deferral for completion of some or all studies contained in the paediatric investigation plan:	**Yes**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of Administration**	**Packaging**	**Package size**
EU/1/07/418/001	Celsentri	150 mg	Film-coated tablet	Oral use	bottle (HDPE/alu)	180 tablets
EU/1/07/418/002	Celsentri	150 mg	Film-coated tablet	Oral use	blister (PVC/alu)	30 tablets
EU/1/07/418/003	Celsentri	150 mg	Film-coated tablet	Oral use	blister (PVC/alu)	60 tablets
EU/1/07/418/004	Celsentri	150 mg	Film-coated tablet	Oral use	blister (PVC/alu)	90 tablets
EU/1/07/418/005	Celsentri	150 mg	Film-coated tablet	Oral use	blister (PVC/alu)	180 (2 x 90) tablets
EU/1/07/418/006	Celsentri	300 mg	Film-coated tablet	Oral use	bottle (HDPE/alu)	180 tablets
EU/1/07/418/007	Celsentri	300 mg	Film-coated tablet	Oral use	blister (PVC/alu)	30 tablets
EU/1/07/418/008	Celsentri	300 mg	Film-coated tablet	Oral use	blister (PVC/alu)	60 tablets
EU/1/07/418/009	Celsentri	300 mg	Film-coated tablet	Oral use	blister (PVC/alu)	90 tablets
EU/1/07/418/010	Celsentri	300 mg	Film-coated tablet	Oral use	blister (PVC/alu)	180 (2 x 90) tablets