European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 23 March 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for Maribavir (EMEA-000353-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)

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

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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 ViroPharma SPRL on 25 June 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 February 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation – 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 an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan,

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

(4) 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 Paediatric Investigation Plan for Maribavir, tablets, age-appropriate oral formulation, 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 Maribavir, tablets, age-appropriate oral formulation, 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

A waiver for Maribavir, tablets, age-appropriate oral formulation, 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 4

This decision is addressed to ViroPharma SPRL, Bovenburg 124 boite 4, 1150 - Brussels, Belgium.

Done at London, 23 March 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/695898/2008
EMEA-000353-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance:
Maribavir

Condition(s):
Cytomegaloviral disease

Pharmaceutical form(s):
Tablets
Age-appropriate oral formulation

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
ViroPharma SPRL

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, ViroPharma SPRL submitted for agreement to the EMEA on 25 June 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 31 July 2008.

Supplementary information was provided by the applicant on 23 November 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:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,

- to grant a deferral in accordance with Article 21 of said Regulation,

- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. 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 are set out in the Annex I.

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

London, 6 February 2009

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

A. CONDITION(S)

Cytomegaloviral disease

B. WAIVER

The waiver applies to:

- Preterm and term newborn infants (from birth to less than 28 days) and infants from 28 days to less than 3 months, for maribavir, tablets and age-appropriate oral formulation, oral use, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Cytomegaloviral disease

- **Proposed PIP indication**

  Prevention of cytomegaloviral disease in patients at risk.

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

  Children from 3 months to less than 18 years of age.

- **Formulation(s)**

  Tablet, oral use, 100 mg
  Age-appropriate oral formulation, oral use

- **Studies**

Area	Number of studies	Description
Quality	1	Development of age-appropriate oral formulation.
Non-clinical	-	Not applicable.
Clinical	4	• Open-label, single arm, multiple-dose safety, efficacy and PK study of maribavir in the prevention of CMV infection and disease in children who have received a stem cell transplant, from 12 to less than 18 years. • Open-label, single dose safety and pharmacokinetics study of maribavir in children who have received a stem-cell or solid-organ transplant, weigh 20 to 40 kg, and are able to swallow a whole tablet or receive a crushed tablet. • Open-label, single-dose study to evaluate the safety and pharmacokinetics of a liquid formulation of maribavir in children less than 6 years old, at risk of developing CMV disease. • Open-label, multiple-dose, safety, pharmacokinetic, and efficacy study of maribavir in children less than 6 years old, at-risk of developing CMV disease.

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By December 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**