EMA/19909/2013

European Medicines Agency decision

P/0005/2013

of 21 January 2013

on the acceptance of a modification of an agreed paediatric investigation plan for valganciclovir (Valcyte and associated names), (EMEA-000726-PIP01-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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on the acceptance of a modification of an agreed paediatric investigation plan for valganciclovir (Valcyte and associated names), (EMEA-000726-PIP01-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 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 European Medicines Agency's decision P/89/2011 issued on 8 April 2011,

Having regard to the application submitted by Roche Registration Limited on 17 September 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 7 December 2012, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the 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 valganciclovir (Valcyte and associated names), film-coated tablet, powder for oral solution, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Roche Registration Limited, 6 Falcon Way, Shire Park, AL7 1TW - Welwyn Garden City, United Kingdom.

Done at London, 21 January 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/652527/2012

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

EMEA-000726-PIP01-09-M01

Scope of the application

Active substance(s):

Valganciclovir

Invented name:

Valcyte and associated names

Condition(s):

Prevention of infection due to cytomegalovirus in solid organ transplant recipients

Treatment of infection due to cytomegalovirus in immunocompromised patients

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Powder for oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Roche Registration Limited

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Roche Registration Limited submitted to the European Medicines Agency on 17 September 2012 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/89/2011 issued on 8 April 2011.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 10 October 2012.

Scope of the modification

Some measures of the Paediatric Investigation Plan 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 changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   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 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, 7 December 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition: Treatment of infection due to cytomegalovirus in immunocompromised patients

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for film-coated tablet, powder for oral solution, 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(s).

2. Paediatric Investigation Plan

2.1. Condition: Prevention of infection due to cytomegalovirus in solid organ transplant recipients

2.2. Indication(s) targeted by the PIP

Prevention of CMV infection in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor.

2.3. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 17 years of age.

2.4. Pharmaceutical form(s)

Film-coated tablet.

Powder for oral solution.

2.5. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	2	Study 1: Multicenter, open label, non-comparator study in renal recipients 4 months to less than 17 years of age. Study 2: Multicenter, open-label, single dose level, non-comparator study in heart transplant recipient less than 4 months of age.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes.
Date of completion of the paediatric investigation plan:	By May 2013.
Deferral for one or more measures contained in the paediatric investigation plan:	No.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of infection due to cytomegalovirus in solid organ transplant recipients

   Authorised indication:

   - Adult patients: Valcyte is indicated for the prevention of CMV disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor.

2. Treatment of infection due to cytomegalovirus in immunocompromised patients

   Authorised indication:

   - Adult patients: Valcyte is indicated for the induction and maintenance treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS).

Authorised pharmaceutical formulation(s):

Powder for oral solution, film-coated tablet

Authorised route(s) of administration:

Oral use