EMA/193382/2011

European Medicines Agency decision

P/89/2011

of 8 April 2011

on the agreement of a paediatric investigation plan and on the granting of a waiver for valganciclovir (Valcyte and associated names), (EMEA-000726-PIP01-09) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** 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 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 Roche Registration Ltd on 19 October 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 February 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) 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 valganciclovir (Valcyte and associated names), film-coated tablets, powder for 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 waiver for valganciclovir (Valcyte and associated names), film-coated tablets, powder for 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 Roche Registration Ltd, 6 Falcon Way, Shire Park, Welwyn Garden City AL7 1TW, United-Kingdom.

Done at London, 8 April 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/825540/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMEA-000726-PIP01-09

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 recipient

Treatment of infection due to cytomegalovirus in immunocompromised patients

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablets

Powder for oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Roche Registration Ltd

Information about the authorised medicinal product:

See Annex II

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Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Roche Registration Ltd submitted for agreement to the European Medicines Agency on 19 October 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 19 November 2009.

Supplementary information was provided by the applicant on 6 December 2010.

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 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 occurs only in adult populations.

   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 and the subset(s) of the paediatric population and conditions 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 annex(es) and appendix.

London, 18 February 2011

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 tablets, 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).

1.2. Condition

Prevention of infection due to cytomegalovirus in solid organ transplant recipients

The waiver applies to:

- Preterm and newborns from birth to less than 1 month of age,
- for film-coated tablets, 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.

2.1.1. 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.

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

From 1 month to less than 17 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablets.

Powder for oral solution.

2.1.4. 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

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By May 2013
Deferral for one or more studies 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 recipient

   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 indications:

   Adult patients:

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

Invented name	Strength	Pharmaceutical form	Route of administration
Valcyte and associated names	50 mg/ml	powder for oral solution	Oral use
Valcyte and associated names	450mg	Film-coated tablet	Oral use