EMA/985495/2011

European Medicines Agency decision

P/0021/2012

of 27 January 2012

on the agreement of a paediatric investigation plan for cyclophosphamide (EMEA-000530-PIP02-11) 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 agreement of a paediatric investigation plan for cyclophosphamide (EMEA-000530-PIP02-11) 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 application submitted by Keocyt SAS on 10 May 2011 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 December 2011, in accordance with Article 18 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 agreement of a paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision agreeing a 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

A paediatric investigation plan for cyclophosphamide, soluble tablet, 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

This decision is addressed to Keocyt SAS, 29, rue Chauvelot, 92240 – Malakoff, France.

Done at London, 27 January 2012

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

EMA/PDCO/816625/2011

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

EMEA-000530-PIP02-11

Scope of the application

Active substance(s):

Cyclophosphamide

Condition(s):

Treatment of malignant diseases

Pharmaceutical form(s):

Soluble tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Keocyt SAS

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, KEOCYT SAS submitted for agreement to the European Medicines Agency on 10 May 2011 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 15 June 2011.

Supplementary information was provided by the applicant on 3 October 2011. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

A meeting with the Paediatric Committee took place on 8 December 2011.

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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.

   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 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, 9 December 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

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of malignant diseases

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric malignant diseases including haematological malignancies (including acute leukaemia, malignant non-Hodgkin lymphoma, Hodgkin disease) as well as soft tissue sarcoma (including rhabdomyosarcoma, osteosarcoma and Ewing sarcoma), neuroblastoma and retinoblastoma.

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Soluble tablet.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Development of a soluble tablet to provide an age-appropriate pharmaceutical form for oral use.
Non-clinical	0	Not applicable.
Clinical	2	Study 2: Open-label, randomised, multicentre, active-controlled trial to evaluate pharmacokinetics, toxicity and safety of cyclophosphamide soluble tablet compared with authorised cyclophosphamide products in children from 6 months to less than 18 years of age with a malignant disease. Study 3: Physiology-based pharmacokinetic model with simulations, applicable to children from birth on.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2015
Deferral for one or more studies contained in the paediatric investigation plan:	No