



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/130187/2012

European Medicines Agency decision P/0043/2012

of 28 February 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for elacytarabine (EMEA-001121-PIP01-10) 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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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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Clavis Pharma ASA on 14 February 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 January 2012, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation 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 deferral 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 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 elacytarabine, dispersion for infusion, intravenous 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 elacytarabine, dispersion for infusion, intravenous 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 elacytarabine, dispersion for infusion, intravenous 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 Clavis Pharma ASA, Parkveien 53B, NO-0256 Oslo, Norway.

Done at London, 28 February 2012

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/926010/2011

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

EMA-001121-PIP01-10

Scope of the application

Active substance(s):

Elacytarabine

Condition(s):

Treatment of acute myeloid leukaemia

Pharmaceutical form(s):

Dispersion for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Clavis Pharma ASA

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Clavis Pharma ASA submitted for agreement to the European Medicines Agency on 14 February 2011 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 18 May 2011.

Supplementary information was provided by the applicant on 24 October 2011. The applicant proposed modifications to the paediatric investigation plan and to the request for a waiver.



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 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 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 annex and appendix.

London, 13 January 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 acute myeloid leukaemia (AML)

The waiver applies to:

- the paediatric population from birth to less than 28 days of age;
- for the dispersion for infusion, for intravenous 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.

Paediatric Investigation Plan

1.2. Condition: Treatment of acute myeloid leukaemia (AML)

1.2.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with refractory or relapsed acute myeloid leukaemia (AML) in combination with liposomal daunorubicin.

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

From 1 year to less than 18 years of age.

1.2.3. Pharmaceutical form(s)

Dispersion for infusion.

1.2.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Development of an elacytarabine formulation not requiring filtration
Non-clinical	1	Study 2: Compatibility and interaction of elacytarabine with liposomal daunorubicin
Clinical	2	Study 3: Open-label, uncontrolled, dose-escalating trial to evaluate the safety, tolerability and pharmacokinetics of elacytarabine in paediatric patients from 1 month to less than 18 years of age with refractory or relapsed acute leukaemia Study 4: Open-label, externally controlled trial to evaluate the safety, activity and efficacy of elacytarabine in combination with liposomal daunorubicin compared to fludarabine, cytarabine and daunorubicin in paediatric patients from 1 month to less than 18 years of age with refractory or relapsed acute myeloid leukaemia with an initial dose-escalating stage to evaluate the safety of elacytarabine in combination with liposomal daunorubicin

2. 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 September 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes