EMA/187577/2013

European Medicines Agency decision

P/0103/2013

of 30 April 2013

on the acceptance of a modification of an agreed paediatric investigation plan for pixantrone (dimaleate) (Pixuvri), (EMEA-000713-PIP02-10-M02) 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 pixantrone (dimaleate) (Pixuvri), (EMEA-000713-PIP02-10-M02) 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/242/2010 issued on 16 November 2010 and the decision P/0036/2012 issued on 13 February 2012,

Having regard to the application submitted by CTI Life Sciences, Ltd on 17 December 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 March 2013, 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 pixantrone (dimaleate) (Pixuvri), powder for concentrate for solution for infusion, intravenous 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 CTI Life Sciences, Ltd., BioPark, Broadwater Road, AL 73 3AX Welwyn Garden City, Hertsfordshire, United Kingdom.

Done at London, 30 April 2013

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

EMA/PDCO/114903/2013 Corr

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

EMEA-000713-PIP02-10-M02

Scope of the application

Active substance(s):

Pixantrone (dimaleate)

Invented name:

Pixuvri

Condition(s):

Treatment of non-Hodgkin lymphoma

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

CTI Life Sciences, Ltd

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, CTI Life Sciences, Ltd submitted to the European Medicines Agency on 17 December 2012 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/242/2010 issued on 16 November 2010 and the decision P/0036/2012 issued on 13 February 2012.

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

The procedure started on 16 January 2013.

Scope of the modification

Timelines of 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 Norwegian Paediatric Committee member agrees 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 annex(es) and appendix.

London, 15 March 2013

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 non-Hodgkin lymphoma

The waiver applies to:

- Infants from birth to less than 6 months of age;
- for powder for concentrate for solution 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(s).

2. Paediatric Investigation Plan

2.1. Condition: Treatment of non-Hodgkin lymphoma

2.1.1. Indication(s) targeted by the PIP

Pixantrone (dimaleate) in combination therapy for the treatment of non-Hodgkin lymphoma in paediatric patients aged 5 years to less than 18 years

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion

2.1.4. Measures

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	3	Measure 1: Mice cardiotoxicity study Measure 2: Toxicokinetics of sudden death mice Measure 3: Evaluation of pixantrone efficacy in vivo xenograft models of paediatric solid tumours
Clinical	3	Measure 4: Open-label, non-controlled, multi-centre, dose-escalation trial to evaluate pharmacokinetics, safety and tolerability of pixantrone in children from 6 months to less than 18 years with lymphoid malignancies and malignant solid tumours Measure 5: Open-label, non-controlled trial to evaluate pharmacokinetics, safety and activity of pixantrone in a combination chemotherapy regimen in children from 5 years to less than 18 years with non-Hodgkin lymphoma and / or malignant solid tumours

Area	Number of studies	Description
		Measure 6: Open-label, randomised, active-controlled, multi-centre trial to evaluate safety and efficacy of pixantrone in children from 5 years to less than 18 years with non-Hodgkin lymphoma and / or malignant solid tumours

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 November 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of non-Hodgkin lymphoma

   Authorised indication(s):

   - Pixuvri is indicated as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non Hodgkin B-cell Lymphomas (NHL).
     The benefit of pixantrone treatment has not been established in patients when used as fifth line or greater chemotherapy in patients who are refractory to last therapy.

Authorised pharmaceutical form(s):

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use