EMA/316519/2017

European Medicines Agency decision

P/0139/2017

of 7 June 2017

on the acceptance of a modification of an agreed paediatric investigation plan for olaratumab (Lartruvo), (EMEA-001760-PIP01-15-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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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/0290/2015 issued on 27 November 2015 and the decision P/0299/2016 issued on 4 November 2016,

Having regard to the application submitted by Eli Lilly and Company Limited on 27 January 2017 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 21 April 2017, 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 olaratumab (Lartruvo), 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 Eli Lilly and Company Limited, Lilly Research Centre, Erl Wood Manor, Sunninghill Road, GU20 6PH - Windlesham, Surrey, United Kingdom.

EMA/PDCO/95563/2017
London, 21 April 2017

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

EMEA-001760-PIP01-15-M02

Scope of the application

Active substance(s):

Olaratumab

Invented name:

Lartruvo

Condition(s):

Treatment of soft tissue sarcoma

Treatment of osteosarcoma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Eli Lilly and Company 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, Eli Lilly and Company Limited submitted to the European Medicines Agency on 27 January 2017 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/0290/2015 issued on 27 November 2015 and the decision P/0299/2016 issued on 4 November 2016.

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

The procedure started on 21 February 2017.

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 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 annexes and appendix.

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 (PIP)

1. Waiver

1.1. Condition:

Treatment of osteosarcoma

The waiver applies to:

- the paediatric population from birth to less than 5 years of age;
- 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 soft tissue sarcoma

2.1.1. Indication(s) targeted by the PIP

Treatment of recurrent rhabdomyosarcoma in children aged from birth to less than 18 years in combination with a standard-of-care chemotherapy regimen.

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)

Concentrate for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	3	**Study 1:** Pilot juvenile non-clinical study to support use of olaratumab in paediatric patients of less than 4 years of age. **Study 2:** In vivo non-clinical efficacy study. **Study 6 (added in this modification)** Definitive juvenile non-clinical study to support use of olarutumab in paediatric patients of less than 4 years of age.

Clinical studies	2	**Study 3:** Open-label, multi-centre, multiple-dose trial to investigate the pharmacokinetics, toxicity and safety and to observe any anti-tumour activity of olaratumab as single agent and as add-on to anti-cancer medicines in paediatric patients from birth to less than 18 years of age with a solid malignant tumour **Study 4:** Multi-centre, randomised, placebo-controlled, double-blind study to evaluate safety and efficacy of olaratumab in combination with a chemotherapy regimen either in paediatric patients from 5 years to less than 18 years with an advanced or metastatic newly-diagnosed osteosarcoma or in paediatric patients from birth to less than 18 years with an advanced or metastatic recurrent rhabdomyosarcoma
Extrapolation, modelling and simulation studies	1	**Study 5:** Paediatric population pharmacokinetic analysis
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition:

Treatment of osteosarcoma

2.2.1. Indication(s) targeted by the PIP

First-line treatment of osteosarcoma in children aged from 5 to 18 years in combination with a standard-of-care chemotherapy regimen.

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

From 5 years to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Concentrate for solution for infusion

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	2	**Study 1:** As for condition "Treatment of soft tissue sarcoma."

		Study 2: As for condition "Treatment of soft tissue sarcoma." ***Study 6 (study added in this modification)*** As for condition "Treatment of soft tissue sarcoma."
Clinical studies	2	**Study 3:** As for condition "Treatment of soft tissue sarcoma." **Study 4:** As for condition "Treatment of soft tissue sarcoma."
Extrapolation, modelling and simulation studies	1	**Study 5:** As for condition "Treatment of soft tissue sarcoma."
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2023
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 soft tissue sarcoma

Authorised indication(s):

- Lartruvo is indicated in combination with doxorubicin for the treatment of adult patients with advanced soft tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin.

Authorised pharmaceutical form(s):

Concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use