

EMA/65212/2019

European Medicines Agency decision P/0072/2019

of 22 March 2019

on the acceptance of a modification of an agreed paediatric investigation plan for carotuximab (EMEA-002138-PIP01-17-M01) 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 carotuximab (EMA-002138-PIP01-17-M01) 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 726/2004¹,

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 European Medicines Agency's decision P/0383/2017 issued on 19 December 2017,

Having regard to the application submitted by TRACON Pharma Limited on 23 October 2018 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 1 February 2019, 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 and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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 carotuximab, concentrate for solution for infusion, intravenous use, including changes to the deferral, 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 TRACON Pharma International Limited, 70 Sir John Rogerson's Quay, D02 R296 - Dublin 2, Ireland.

EMA/PDCO/784000/2018
London, 1 February 2019

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002138-PIP01-17-M01

Scope of the application

Active substance(s):

Carotuximab

Condition(s):

Treatment of soft tissue sarcoma

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

TRACON Pharma Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, TRACON Pharma Limited submitted to the European Medicines Agency on 23 October 2018 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/0383/2017 issued on 19 December 2017.

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

The procedure started on 4 December 2018.

Scope of the modification

Some measures and timelines 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 and to the deferral 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 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 soft tissue sarcoma

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of soft tissue sarcoma

2.1.1. Indication(s) targeted by the PIP

Treatment of angiosarcoma

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

From 2 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	0	Not applicable
Clinical studies	2	Study 1: Open-label, active-controlled (adults)/uncontrolled (adolescents), multiple dose trial to evaluate pharmacokinetics, safety and anti-tumour activity of carotuximab in combination with pazopanib in adults and adolescents from 12 to less than 18 years of age with angiosarcoma not amenable to curative surgery (105SAR301).

		Study 2: Open-label, uncontrolled, multiple dose trial to evaluate pharmacokinetics, safety and anti-tumour activity of carotuximab in combination with pazopanib in children from 2 to less than 18 years of age with angiosarcoma not amenable to curative surgery.
Extrapolation, modelling and simulation studies	2	Study 3: Modelling and simulation study to support the use of the carotuximab in children from 2 to less than 18 years of age with angiosarcoma not amenable to curative surgery. Study 4: Extrapolation study to support the use of the carotuximab in children from 2 to less than 18 years of age with angiosarcoma not amenable to curative surgery.
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 July 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes