EMA/467537/2019

European Medicines Agency decision

P/0303/2019

of 10 September 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral for dostarlimab (EMEA-002463-PIP01-18) 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.

European Medicines Agency decision

P/0303/2019

of 10 September 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral for dostarlimab (EMEA-002463-PIP01-18) 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 Tesaro UK Ltd on 7 September 2018 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 26 July 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 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.

(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.

[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 dostarlimab, solution 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 dostarlimab, solution 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

This decision is addressed to Tesaro UK Ltd, 55 Baker Street, W1U 7EU - London, United Kingdom.

EMA/PDCO/272028/2019
Amsterdam, 26 July 2019

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

EMEA-002463-PIP01-18

Scope of the application

Active substance(s):

Dostarlimab

Condition(s):

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid malignancies)

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Tesaro UK Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Tesaro UK Ltd submitted for agreement to the European Medicines Agency on 7 September 2018 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 16 October 2018.

Supplementary information was provided by the applicant on 23 April 2019. The applicant proposed modifications to the paediatric investigation plan and withdrew its 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 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 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 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid malignancies)

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients from birth to less than 18 years old with neuroblastoma and/or osteosarcoma

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)

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	3	**Study 1** Open-label, multiple dose, two part trial to evaluate pharmacokinetics, safety, activity and acceptability of niraparib when given in combination with dostarlimab in children from 6 months of age to less than 18 years of age with relapsed/ refractory solid tumours, excluding central nervous system (CNS) tumours in part 1a and 1b and with relapsed/ refractory osteosarcoma and relapsed/ refractory neuroblastoma in Part 2. **Study 2** Open-label, randomised controlled, active comparator trial to evaluate efficacy and safety of niraparib in combination with dostarlimab against current standard of care in children from 6 months of age to less than 18 years of age with relapsed/ refractory osteosarcoma and/or neuroblastoma.

		Study 3 Open-label, randomised controlled, active comparator trial to evaluate efficacy and safety of niraparib in combination with dostarlimab against current standard of care in children from birth to less than 18 years of age with newly diagnosed high risk osteosarcoma and/or Stage 4 neuroblastoma.
Extrapolation, modelling and simulation studies	1	**Study 4** Modelling and simulation study, to evaluate the use of niraparib and dostarlimab in the proposed paediatric indications in children from birth to less than 18 years of age.
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 June 2040
Deferral for one or more measures contained in the paediatric investigation plan:	Yes