EMA/313775/2019

European Medicines Agency decision

P/0256/2019

of 16 July 2019

on the acceptance of a modification of an agreed paediatric investigation plan for durvalumab (IMFINZI), (EMEA-002028-PIP01-16-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 durvalumab (IMFINZI), (EMEA-002028-PIP01-16-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 726/2004[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/0082/2018 issued on 16 March 2018,

Having regard to the application submitted by AstraZeneca AB on 1 February 2019 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 May 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 durvalumab (IMFINZI), 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 AstraZeneca AB, Forskargatan 18, SE 151 85 - Södertälje Sweden.

EMA/PDCO/170477/2019
Amsterdam, 29 May 2019

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

EMEA-002028-PIP01-16-M01

Scope of the application

Active substance(s):

Durvalumab

Invented name:

IMFINZI

Condition(s):

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue)

Treatment of malignant neoplasms of haematopoietic and lymphoid tissue

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:

AstraZeneca AB

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 1 February 2019 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0082/2018 issued on 16 March 2018.

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

The procedure started on 1 April 2019.

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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue)

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients from birth to less than 18 years old with a paediatric solid tumour

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	1	**Study 1** Non-clinical biomarker study in paediatric tumour tissues.
Clinical studies	2	**Study 2** Multi-centre, open-label study, with a dose finding phase (phase 1) and an expansion phase (phase 2), to evaluate the safety, tolerability, pharmacokinetics and antitumor activity of durvalumab monotherapy, and durvalumab used in combination with tremelimumab in paediatric patients from birth to less than 18 years of age with a relapsed/refractory solid tumour or a relapsed/refractory haematological malignancy including lymphomas and acute leukaemias or a paediatric solid tumour or haematological malignancy for whom no curative standard treatment is available.

Area	Number of measures	Description
		Study 3 Open-label, randomized, active-controlled study to evaluate the efficacy and safety of durvalumab monotherapy, and durvalumab used in combination with tremelimumab in children from birth to less than 18 years of age with a paediatric solid tumour selected on the basis of the results of Study 1 and Study 2.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition:

Treatment of malignant neoplasms of haematopoietic and lymphoid tissue

2.2.1. Indication(s) targeted by the PIP

Treatment of paediatric patients from birth to less than 18 years old with a paediatric haematological malignancy.

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

From birth 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	1	**Study 1** Same as for condition treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue).

Area	Number of measures	Description
Clinical studies	2	**Study 2** Same as for condition treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue). **Study 4** Open-label, randomized, active-controlled study to evaluate the efficacy and safety of durvalumab monotherapy, and durvalumab used in combination with tremelimumab in children from birth to less than 18 years of age with a paediatric haematological malignancy selected on the basis of the results of Study 1 and Study 2.
Extrapolation, modelling and simulation studies	0	Not applicable.
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 September 2027
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 all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue)

Authorised indication(s):

- IMFINZI as monotherapy is indicated for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy.

Authorised pharmaceutical form(s):

Concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use