

EMA/254762/2019

European Medicines Agency decision

P/0193/2019

of 13 May 2019

on the acceptance of a modification of an agreed paediatric investigation plan for isatuximab (EMA-002205-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 isatuximab (EMA-002205-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/0156/2018 issued on 15 June 2018,

Having regard to the application submitted by Sanofi-Aventis Recherche & Développement on 15 January 2019 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 26 April 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.
- (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 isatuximab, 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 Sanofi-Aventis Recherche & Développement, 1 Avenue Pierre Brossolette, 91385 - Chilly Mazarin, France.

EMA/PDCO/100158/2019 **Corr**
Amsterdam, 26 April 2019

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002205-PIP01-17-M01

Scope of the application

Active substance(s):

Isatuximab

Condition(s):

Treatment of malignant neoplasms of the haematopoietic and lymphoid tissue

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Sanofi-Aventis Recherche & Développement

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi-Aventis Recherche & Développement submitted to the European Medicines Agency on 15 January 2019 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/0156/2018 issued on 15 June 2018.

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

The procedure started on 26 February 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 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 malignant neoplasms of the haematopoietic and lymphoid tissue

The waiver applies to:

- the paediatric population from birth to less than 28 days of age;
- concentrate for solution for infusion, intravenous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition

Treatment of malignant neoplasms of the haematopoietic and lymphoid tissue

2.1.1. Indication(s) targeted by the PIP

- Treatment of relapsed, refractory and newly-diagnosed acute lymphoblastic leukaemia in combination with standard treatment in paediatric patients from 28 days to less than 18 years of age
- Treatment of relapsed, refractory and newly-diagnosed acute myeloid leukaemia in combination with standard treatment in paediatric patients from 28 days to less than 18 years of age

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

From 28 days 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 Paediatric preclinical testing study to evaluate the in vitro activity of isatuximab combinations with standards of care in preclinical models of acute myeloid leukaemia .

Clinical studies	3	Study 2 Open-label, single-arm trial to evaluate pharmacokinetics, safety and antitumor activity of isatuximab used in combination with chemotherapy in children from 28 days to less than 18 years of age with relapsed/refractory B or T acute lymphoblastic leukaemia or acute myeloid leukaemia in first or second relapse. Study 3 Open-label, randomised controlled trial to evaluate the safety and efficacy of isatuximab used in combination with chemotherapy compared to chemotherapy in children from 28 days to less than 18 years of age with relapsed/refractory B or T acute lymphoblastic leukaemia or acute myeloid leukaemia in first or second relapse. The population to be included in the study is to be determined according to the results of Study 2. Study 4 Open-label, randomised controlled trial to evaluate the efficacy and safety of isatuximab used in combination with chemotherapy compared to chemotherapy in children from 28 days to less than 18 years of age with newly-diagnosed B or T acute lymphoblastic leukaemia or newly-diagnosed acute myeloid leukaemia. The population to be included in the study is to be determined according to the results of Study 3.
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:	No
Date of completion of the paediatric investigation plan:	By December 2032
Deferral for one or more measures contained in the paediatric investigation plan:	Yes