EMA/851802/2022

European Medicines Agency decision

P/0494/2022

of 2 December 2022

on the acceptance of a modification of an agreed paediatric investigation plan for isatuximab (Sarclisa), (EMEA-002205-PIP01-17-M03) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0156/2018 issued on 15 June 2018, the decision P/0193/2019 issued on 13 May 2019 and the decision P/0185/2021 issued on 10 May 2021,

Having regard to the application submitted by Sanofi-Aventis Recherche & Développement on 29 June 2022 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 14 October 2022, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for isatuximab (Sarclisa), 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 Sanofi-Aventis Recherche & Développement, 1 avenue Pierre Brossolette, 91385 - Chilly-Mazarin, France.

EMA/PDCO/637919/2022
Amsterdam, 14 October 2022

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

EMEA-002205-PIP01-17-M03

Scope of the application

Active substance(s):

Isatuximab

Invented name and authorisation status:

See Annex II

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

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 29 June 2022 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 decision P/0193/2019 issued on 13 May 2019 and the decision P/0185/2021 issued on 10 May 2021.

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

The procedure started on 16 August 2022.

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 Paediatric Committee member of Norway 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 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

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	**Description**
Quality-related studies	Not applicable
Non-clinical studies	**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	**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	Not applicable
Other studies	Not applicable
Other measures	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 August 2035
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of malignant neoplasms of the haematopoietic and lymphoid tissue

Authorised indication(s):

- in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy
  - Invented name(s): Sarclisa
  - Authorised pharmaceutical form(s): Concentrate for solution for infusion
  - Authorised route(s) of administration: Intravenous use
  - Authorised via centralised procedure
- in combination with carfilzomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy
  - Invented name(s): Sarclisa
  - Authorised pharmaceutical form(s): Concentrate for solution for infusion
  - Authorised route(s) of administration: Intravenous use
  - Authorised via centralised procedure