EMADOC-1700519818-3003858 Corr[1]

European Medicines Agency decision

EMA/PE/0000181993

of 8 November 2024

on the acceptance of a modification of an agreed paediatric investigation plan for mosunetuzumab (Lunsumio) 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.

[1] 20 March 2026, Corrigendum of EMA Decision, previous Doc Ref Id EMADOC-1700519818-1735100, on front page invented name added and decision number format corrected

European Medicines Agency decision

EMA-PE-0000181993

of 8 November 2024

on the acceptance of a modification of an agreed paediatric investigation plan for mosunetuzumab (Lunsumio), 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[2],

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[3],

Having regard to the European Medicines Agency's decision P/0108/2020 issued on 20 March 2020,

Having regard to the application submitted by Roche Registration GmbH on 8 July 2024 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 18 October 2024, 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.

[2] OJ L 378, 27.12.2006, p.1, as amended.
[3] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for mosunetuzumab (Lunsumio), concentrate for solution for infusion, solution for injection, intravenous use, subcutaneous 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 Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 - Grenzach-Wyhlen, Germany.

EMADOC-1700519818-1622834 Corr[1]
Amsterdam, 18 October 2024

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

EMA/PE/0000181993

Scope of the application

Active substance(s):

Mosunetuzumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of mature B-cell neoplasms

Pharmaceutical form(s):

Concentrate for solution for infusion

Solution for injection

Route(s) of administration:

Intravenous use

Subcutaneous use

Name/corporate name of the PIP applicant:

Roche Registration GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Roche Registration GmbH submitted to the European Medicines Agency on 8 July 2024 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/0108/2020 issued on 20 March 2020.

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

[1] 5 November 2024

The procedure started on 19 August 2024.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

A new pharmaceutical form and a new route of administration were added.

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 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 mature B-cell neoplasms

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- concentrate for solution for infusion, intravenous use; solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Treatment of mature B-cell neoplasms

2.1.1. Indication(s) targeted by the PIP

Treatment of children with relapsed or refractory high-grade mature B-cell non-Hodgkin lymphoma (B-NHL), including Burkitt lymphoma (BL), Burkitt leukaemia (mature B-cell acute lymphoblastic leukaemia FAB L3; B-AL), and diffuse large B-cell lymphoma (DLBCL).

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

From 6 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Concentrate for solution for infusion; solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	Open-label, single-arm, two-part trial to evaluate safety, tolerability, pharmacokinetics (PK), and antitumor activity of mosunetuzumab in combination with chemotherapy in children from 6 months to less than 18 years of age with relapsed/refractory (R/R) mature B-cell non-Hodgkin lymphoma (B-NHL). Part 2 (cohort expansion) is gated on Part 1 results (safety, PK, and preliminary antitumor activity).

Extrapolation, modelling and simulation studies	Modelling and simulation study to determine the dose of the product in the proposed paediatric indication in children from 6 months to less than 18 years of age with relapsed/refractory (R/R) mature B-cell non-Hodgkin lymphoma (B-NHL).
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:	Yes
Date of completion of the paediatric investigation plan:	By June 2027
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 follicular lymphoma

Authorised indication(s):

- Lunsumio as monotherapy is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior systemic therapies.
  - Invented name(s): Lunsumio
  - Authorised pharmaceutical form(s): concentrate for solution for infusion
  - Authorised route(s) of administration: intravenous use
  - Authorised via centralised procedure