EMA/210429/2023

European Medicines Agency decision

P/0197/2023

of 15 May 2023

on the acceptance of a modification of an agreed paediatric investigation plan for odronextamab (EMEA-003149-PIP01-21-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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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/0426/2022 issued on 28 October 2022,

Having regard to the application submitted by Regeneron Ireland DAC on 23 January 2023 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 26 April 2023, 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, 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 odronextamab, 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 Regeneron Ireland DAC, One Warrington Place, D02 HH27 - Dublin Ireland.

EMA/PDCO/41666/2023
Amsterdam, 26 April 2023

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

EMEA-003149-PIP01-21-M01

Scope of the application

Active substance(s):

Odronextamab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of mature B cell malignancies

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Regeneron Ireland DAC

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Regeneron Ireland DAC submitted to the European Medicines Agency on 23 January 2023 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0426/2022 issued on 28 October 2022.

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

The procedure started on 27 February 2023.

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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of mature B cell malignancies

2.1.1. Indication(s) targeted by the PIP

Treatment of relapsed/ refractory aggressive mature B- cell Non-Hodking Lymphoma (NHL) including Burkitt lymphoma (BL), diffuse large B-cell lymphoma (DLBCL) and primary mediastinal B-cell lymphoma (PMBL) in paediatric patients from birth to less than 18 years of age

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	**Description**
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	**Study 1 (Glo-BNHL master protocol - Cohort 1a and 1b - EudraCT 2021-004283-10)** Open-label two part, two cohort trial to evaluate a recommended phase 2 dose (RP2D), pharmacokinetics, pharmacodynamics, safety (part 1) and activity and immunogenicity (part 2) of odronextamab in children from birth to less than 18 years of age (and adults) with relapsed refractory (r/r) aggressive mature B-NHL in first relapsed (cohort 1a) and r/r aggressive mature B-NHL in second or higher relapse (cohort 1b)
Extrapolation, modelling and simulation studies	**Study 2** Modelling and simulation study to support the use of odronextamab in the patients from birth to less than 18 years of age (and adults) with relapsed/refractory aggressive mature 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 March 2028
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:

The product is not authorised anywhere in the European Community.