

EMA/825329/2022

European Medicines Agency decision P/0426/2022

of 28 October 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral for odronextamab (EMA-003149-PIP01-21) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Regeneron Ireland DAC on 19 November 201 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 September 2022, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for odronextamab, solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for odronextamab, solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Regeneron Ireland DAC, One Warrington Place, D02 HH27 – Dublin, Ireland.

EMA/PRAC/573136/2022
Amsterdam, 9 September 2022

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMA-003149-PIP01-21

Scope of the application

Active substance(s):

Odronextamab

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 16(1) of Regulation (EC) No 1901/2006 as amended, Regeneron Ireland DAC submitted for agreement to the European Medicines Agency on 19 November 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 4 January 2022.

Supplementary information was provided by the applicant on 27 May 2022.

The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation.
- to grant a deferral in accordance with Article 21 of said Regulation.

The Paediatric Committee member Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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

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), primary mediastinal B-cell lymphoma (PMBL) and B-lymphoblastic lymphoma 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