

EMA/184305/2023

European Medicines Agency decision P/0191/2023

of 26 May 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for ocrelizumab (Ocrevus), (EMA-000310-PIP05-22) 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 Roche Registration GmbH on 4 July 2022 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 31 March 2023, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 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 and on the granting of a waiver.
- (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.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

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 ocrelizumab (Ocrevus), solution for injection, subcutaneous 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 ocrelizumab (Ocrevus), solution for injection, subcutaneous 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

A waiver for ocrelizumab (Ocrevus), solution for injection, subcutaneous 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 4

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/159/2011 issued on 4 July 2011, including subsequent modifications thereof.

Article 5

This decision is addressed to Roche Registration GmbH, Emil-Barell-Strasse 1, D-79639 - Grenzach-Wyhlen, Germany.

EMA/PDCO/7788/2023
Amsterdam, 31 March 2023

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

EMA-000310-PIP05-22

Scope of the application

Active substance(s):

Ocrelizumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of multiple sclerosis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Roche Registration GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Roche Registration GmbH submitted for agreement to the European Medicines Agency on 4 July 2022 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 16 August 2022.

Supplementary information was provided by the applicant on 13 December 2022. The applicant proposed modifications to the paediatric investigation plan.

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;
 - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Paediatric Committee member of 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 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 multiple sclerosis

The waiver applies to:

- the paediatric population from birth to less than 10 years of age;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of multiple sclerosis

2.1.1. Indication(s) targeted by the PIP

Treatment of relapsing remitting multiple sclerosis (RRMS)

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

From 10 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 Open-label trial to evaluate pharmacokinetics of ocrelizumab administered subcutaneously in children from 10 years to less than 18 years of age with relapsing remitting multiple sclerosis.
Modelling and simulation studies	Study 2 Population pharmacokinetic (PPK) model to evaluate the use of ocrelizumab administered subcutaneously in children from 10 years to less than 18 years of age with relapsing remitting multiple sclerosis.
Other studies	Not applicable

Extrapolation plan	Subcutaneous studies CN41144 (Ocarina I) and CN42097 (Ocarina II) in adult multiple sclerosis patients and intravenous studies WA39085 (Operetta 1) and WN42086 (Operetta 2) in paediatric multiple sclerosis patients are part of the extrapolation plan of efficacy data of the intravenous pharmaceutical form to the subcutaneous pharmaceutical form for the paediatric population from 10 years to less than 18 years of age, as agreed by the PDCO.
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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 August 2029
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 multiple sclerosis

Authorised indication(s):

- For the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.
 - Invented name(s): Ocrevus
 - Authorised pharmaceutical form(s): Concentrate for solution for infusion
 - Authorised route(s) of administration: Intravenous use
 - Authorised via centralised procedure
- For the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity
 - Invented name(s): Ocrevus
 - Authorised pharmaceutical form(s): Concentrate for solution for infusion
 - Authorised route(s) of administration: Intravenous use
 - Authorised via centralised procedure