EMA/286493/2023

European Medicines Agency decision

P/0248/2023

of 14 July 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for immunoglobulin G4 [224-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5713 γ4-chain), disulphide with human monoclonal REGN5713 κ-chain, dimer (REGN5713) / Immunoglobulin G4 [227-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5714 γ4-chain), disulphide with human monoclonal REGN5714 κ-chain, dimer (REGN5714) / Immunoglobulin G4 [228-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5715 γ4-chain), disulphide with human monoclonal REGN5715 κ-chain, dimer (REGN5715), (EMEA-003270-PIP01-22) 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.

European Medicines Agency decision

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of 14 July 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for immunoglobulin G4 [224-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5713 γ4-chain), disulphide with human monoclonal REGN5713 κ-chain, dimer (REGN5713) / Immunoglobulin G4 [227-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5714 γ4-chain), disulphide with human monoclonal REGN5714 κ-chain, dimer (REGN5714) / Immunoglobulin G4 [228-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5715 γ4-chain), disulphide with human monoclonal REGN5715 κ-chain, dimer (REGN5715), (EMEA-003270-PIP01-22) 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[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 application submitted by Regeneron Ireland DAC on 30 June 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 26 May 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 immunoglobulin G4 [224-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5713 γ4-chain), disulphide with human monoclonal REGN5713 κ-chain, dimer (REGN5713) / Immunoglobulin G4 [227-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5714 γ4-chain), disulphide with human monoclonal REGN5714 κ-chain, dimer (REGN5714) / Immunoglobulin G4 [228-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5715 γ4-chain), disulphide with human monoclonal REGN5715 κ-chain, dimer (REGN5715), 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 immunoglobulin G4 [224-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5713 γ4-chain), disulphide with human monoclonal REGN5713 κ-chain, dimer (REGN5713) / Immunoglobulin G4 [227-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5714 γ4-chain), disulphide with human monoclonal REGN5714 κ-chain, dimer (REGN5714) / Immunoglobulin G4 [228-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5715 γ4-chain), disulphide with human monoclonal REGN5715 κ-chain, dimer (REGN5715), 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 immunoglobulin G4 [224-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5713 γ4-chain), disulphide with human monoclonal REGN5713 κ-chain, dimer (REGN5713) / Immunoglobulin G4 [227-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5714 γ4-chain), disulphide with human monoclonal REGN5714 κ-chain, dimer (REGN5714) / Immunoglobulin G4 [228-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5715 γ4-chain), disulphide with human monoclonal REGN5715 κ-chain, dimer (REGN5715), 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 is addressed to Regeneron Ireland DAC, One Warrington Place, Dublin 2, D02 HH27 – Dublin, Ireland.

EMA/PDCO/88958/2023
Amsterdam, 26 May 2023

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

EMEA-003270-PIP01-22

Scope of the application

Active substance(s):

Immunoglobulin G4 [224-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5713 γ4-chain), disulphide with human monoclonal REGN5713 κ-chain, dimer (REGN5713) /

Immunoglobulin G4 [227-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5714 γ4-chain), disulphide with human monoclonal REGN5714 κ-chain, dimer (REGN5714) /

Immunoglobulin G4 [228-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5715 γ4-chain), disulphide with human monoclonal REGN5715 κ-chain, dimer (REGN5715)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of allergic rhinitis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous 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 30 June 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.

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 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

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 allergic rhinitis

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- solution for injection, subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of allergic rhinitis

2.1.1. Indication(s) targeted by the PIP

Treatment of allergic rhinitis with or without conjunctivitis in birch tree pollen allergic paediatric patients

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

From 2 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	**Study 1** Development of an age-appropriate liquid formulation for use in paediatric patients from 2 years to less than 18 years of age.
Non-clinical studies	Not applicable
Clinical studies	**Study 2** (R5713-5714-5715-ALG-TBD) Double-blind, randomised, single dose, placebo controlled trial to evaluate pharmacokinetics, safety and efficacy of REGN5713/ REGN5714/ REGN5715 in children from 6 years to less than 18 years of age with allergic rhinitis (with or without allergic conjunctivitis) due to birch pollen.

	Study 3 (R5713-5714-5715-ALG-TBD2) Double-blind, randomised, single dose, placebo controlled trial to evaluate pharmacokinetics and safety of REGN5713/ REGN5714/ REGN5715 in children from 2 years to less than 6 years of age with allergic rhinitis (with or without allergic conjunctivitis) due to birch pollen.
Modelling and simulation studies	**Study 4** Modelling and simulation study, to evaluate the use of REGN5713/ REGN5714/ REGN5715 in allergic rhinitis (with or without allergic conjunctivitis) due to birch pollen in children from 2 years to less than 18 years of age.
Other studies	Not applicable
Extrapolation plan	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 December 2031
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.