EMA/2822/2016

European Medicines Agency decision

P/0037/2016

of 12 February 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for recombinant human antibody against the respiratory syncytial virus fusion protein (REGN2222), (EMEA-001747-PIP01-15) 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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on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for recombinant human antibody against the respiratory syncytial virus fusion protein (REGN2222), (EMEA-001747-PIP01-15) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Regeneron Ireland on 13 March 2015 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 11 December 2015, in accordance with Article 18 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for recombinant human antibody against the respiratory syncytial virus fusion protein (REGN2222), solution for injection, intramuscular use, 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 recombinant human antibody against the respiratory syncytial virus fusion protein (REGN2222), solution for injection, intramuscular use, 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

A waiver for recombinant human antibody against the respiratory syncytial virus fusion protein (REGN2222), solution for injection, intramuscular use, 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 4

This decision is addressed to Regeneron Ireland, Europa House, Block 9 Harcourt Centre, Harcourt Street, 2 Dublin, Ireland.

Done at London, 12 February 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/576162/2015 Corr
London, 11 December 2015

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

EMEA-001747-PIP01-15

Scope of the application

Active substance(s):

Recombinant human antibody against the respiratory syncytial virus fusion protein (REGN2222)

Condition(s):

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intramuscular use

Intravenous use

Name/corporate name of the PIP applicant:

Regeneron Ireland

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Regeneron Ireland submitted for agreement to the European Medicines Agency on 13 March 2015 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 21 April 2015.

Supplementary information was provided by the applicant on 24 August 2015. The applicant proposed modifications to the paediatric investigation plan.

A meeting with the Paediatric Committee took place on 9 December 2015.

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 18 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 Norwegian Paediatric Committee member 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

1.1. Condition:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)

The waiver applies to:

- the paediatric population from 2 years to less than 18 years of age;
- solution for injection, intramuscular use, and intravenous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)

2.1.1. Indication(s) targeted by the PIP

Prevention of serious respiratory syncytial virus lower respiratory tract infection in children at risk for serious disease

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

From birth to less than 2 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age appropriate intravenous (i.v.) formulation for children with chronic underlying disease who are hospitalised and already have i.v. access
Non-clinical studies	0	Not applicable.

Area	Number of measures	Description
Clinical studies	5	**Study 2** Double-blind placebo-controlled, 2-part PK, efficacy and safety study in healthy preterm infants less than or equal to 35 weeks and 6 days gestation and less than or equal to 6 months of chronological age at the start of the RSV season, not eligible for palivizumab prophylaxis **Study 3** Double-blind placebo-controlled efficacy and safety study in healthy full term and preterm infants less than or equal to 6 months of chronological age at the start of the RSV season, not eligible for palivizumab prophylaxis. **Study 4** Double-blind, active-controlled safety and efficacy study in infants who are recommended to receive palivizumab for prophylaxis including those with chronic lung disease (CLD) and other chronic underlying medical conditions (except haemodynamically-significant congenital heart disease) and who are less than or equal to 24 months of age or preterm infants without CLD less than or equal to 6 months of age at the start of the RSV season. **Study 5** Double-blind, active-controlled safety and efficacy study in infants with haemodynamically-significant congenital heart disease (CHD) or other chronic underlying medical conditions (excluding CLD) who are recommended to receive RSV prophylaxis and who are less than or equal to 24 months of age at the start of the RSV season. **Study 6** Observational, double-blind, 1-year extension study to compare the incidence of clinically-significant wheezing in infants who received REGN2222 compared to infants who did not receive any RSV prophylaxis during the same RSV season.

Area	Number of measures	Description
Extrapolation, modelling and simulation studies	2	**Study 7** Modelling and simulation study to optimise appropriate intramuscular dose regimens that will result in a protective concentration against RSV during the dose interval and the remaining of the RSV season in infants and children less than or equal to 24 months of age at the start of the RSV season. **Study 8** Extrapolation study to estimate efficacy of REGN2222 in children less than or equal to 24 months of age at the start of the RSV season who are eligible for palivizumab prophylaxis or who have underlying chronic medical conditions for the prevention of serious lower respiratory tract infection due to respiratory syncytial virus
Other studies	0	Not applicable.
Other measures	0	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 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes