EMA/203434/2013

European Medicines Agency decision

P/0111/2013

of 30 April 2013

on the agreement of a paediatric investigation plan and on the granting of a waiver for palivizumab (Synagis) (EMEA-001309-PIP01-12) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 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 AbbVie Ltd on 10 December 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 March 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 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 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 palivizumab (Synagis), solution for injection, powder and solvent for solution for injection, intramuscular 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 waiver for palivizumab (Synagis), solution for injection, powder and solvent for solution for injection, intramuscular 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 AbbVie Ltd, Vanwall Business Park, SL6 4XE – Maidenhead, United Kingdom.

Done at London, 30 April 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/106977/2013

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

EMEA-001309-PIP01-12

Scope of the application

Active substance(s):

Palivizumab

Invented name:

Synagis

Condition(s):

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

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Powder and solvent for solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

AbbVie Ltd

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, AbbVie Ltd submitted for agreement to the European Medicines Agency on 10 December 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 16 January 2013.

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 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 annexes and appendix.

London, 15 March 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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;
- for solution for injection, powder and solvent for solution for injection; intramuscular 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: Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)

2.1.1. Indication(s) targeted by the PIP

Prevention of serious lower respiratory tract disease caused by RSV in

- Children born at 35 weeks of gestation or less and less than 6 months of age at the onset of the RSV season.
- Children less than 2 years of age and requiring treatment for bronchopulmonary dysplasia within the last 6 months.
- Children less than 2 years of age and with haemodynamically significant congenital heart 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	1	Measure 1 Development of an age-appropriate liquid formulation for palivizumab (solution for injection).
Non-clinical	0	Not applicable.

Area	Number of measures	Description
Clinical	2	Measure 2 Double-Blind, randomized study to evaluate the safety, tolerability, and pharmacokinetics of a new liquid formulation of palivizumab in healthy adult volunteers. Measure 3 Randomized, double-blind, two-period, cross-over study to evaluated the pharmacokinetics, safety and tolerability of a liquid formulation of palivizumab in children below the age of 6 months with a history of prematurity (born at or below 35 weeks gestational age).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By July 2004.
Deferral for one or more measures contained in the paediatric investigation plan:	No.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of lower respiratory tract disease caused by RSV

   Authorised indication(s):

   Synagis is indicated for the prevention of serious lower respiratory tract disease requiring hospitalisation caused by respiratory syncytial virus (RSV) in children at high risk for RSV disease:

   - Children born at 35 weeks of gestation or less and less than 6 months of age at the onset of the RSV season.
   - Children less than 2 years of age and requiring treatment for bronchopulmonary dysplasia within the last 6 months.
   - Children less than 2 years of age and with haemodynamically significant congenital heart disease.

Authorised pharmaceutical form(s):

Powder and solvent for solution for injection

Authorised route(s) of administration:

Intramuscular use