EMA/644824/2010

European Medicines Agency decision

P/212/2010

of 29 October 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for pagibaximab (EMEA-000608-PIP01-09) 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 726/2004[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 Biosynexus, Incorporated on 14 July 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting 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 10 September 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and of its own motion in accordance with 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 pagibaximab, 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 pagibaximab, 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

A waiver for pagibaximab, 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 4

This decision is addressed to Biosynexus, Incorporated, 9298 Gaither Road, MD 20877, Gaithersburg, The United States.

Done at London, 29 October 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/530566/2010

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

EMA-000608-PIP01-09

Scope of the application

Active substance(s):

Pagibaximab

Condition(s):

Prevention of bacterial sepsis

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Biosynexus, Incorporated

Basis for opinion

Pursuant to article 16(1) of Regulation (EC) No 1901/2006 as amended, Biosynexus Incorporated submitted for agreement to the European Medicines Agency on 14 July 2009 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 17 September 2009.

Supplementary information was provided by the applicant on 28 June 2010.

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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 on its own motion 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 Icelandic and the Norwegian Paediatric Committee members do agree 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(es) and appendix.

London, 10 September 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

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

1. Condition(s)

Prevention of bacterial sepsis

2. Waiver

2.1. Condition(s)

Prevention of bacterial sepsis

2.1.1. Indication(s)

The waiver applies to:

- preterm newborn infants weighing more than 1200 g at birth,
- term newborn infants and children (from birth to less than 18 years),

on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Prevention of bacterial sepsis

3.1.1. Indication(s) targeted by the PIP

Prevention of bacterial sepsis in very low birth weight preterm newborns

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

Preterm newborns with body weight from 500g to less than or equal to 1200g

3.1.3. Pharmaceutical form(s)

Solution for infusion

3.1.4. Studies

Area	Number of studies	Description
Quality	N/A	Not applicable.
Non-clinical	N/A	Not applicable.
Clinical	3	Study 1: A multi-centre, randomized, double-blind, placebo controlled trial to evaluate the safety and efficacy of pagibaximab injection in very low birth weight neonates for the prevention of staphylococcal sepsis

		(MAB-N007) Study 2: A multi-centre, randomized, double-blind, placebo controlled trial to evaluate the safety and efficacy of pagibaximab injection in very low birth weight neonates for the prevention of staphylococcal sepsis (MAB-N008) Study 3: Pharmacokinetics and safety, open label multiple dose trial to evaluate the pharmacokinetics and safety of pagibaximab injection in very low birth weight neonates weighing from 500 g to less than 600 g at birth for the prevention of staphylococcal sepsis

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues, efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By January 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes