EMA/169122/2014

European Medicines Agency decision

P/0091/2014

of 4 April 2014

on the acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (EMEA-000558-PIP01-09-M02) 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 acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (EMEA-000558-PIP01-09-M02) 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 European Medicines Agency's decision P/184/2009 issued on 7 September 2009, and the decision P/0197/2012 issued on 24 August 2012,

Having regard to the application submitted by LFB Biotechnologies on 13 December 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 March 2014, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for human normal immunoglobulin, solution for infusion, intravenous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to LFB Biotechnologies, 3, avenue des Tropiques B.P. 40305- Les Ulis, 91958 - Courtaboeuf Cedex, France.

Done at London, 4 April 2014

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

EMA/PDCO/18113/2014

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000558-PIP01-09-M02

Scope of the application

Active substance(s):

Human normal immunoglobulin

Condition(s):

Treatment of primary immunodeficiency (PID)

Treatment of idiopathic thrombocytopenic purpura (ITP)

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

LFB Biotechnologies

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, LFB Biotechnologies submitted to the European Medicines Agency on 13 December 2013 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/184/2009 issued on 7 September 2009, and the decision P/0197/2012 issued on 24 August 2012.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 21 January 2014.

Scope of the modification

Some measures and/or timelines of the Paediatric Investigation Plan have been modified.

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Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the 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.

London, 21 March 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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: treatment of primary immunodeficiency (PID)

Primary immunodeficiency (PID) as model for replacement therapy.

This covers replacement therapy in:

- primary immunodeficiency syndromes;
- myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinemia and recurrent infections;
- children with congenital AIDS and recurrent infections.

The waiver applies to:

- all subsets of the paediatric population from birth to less than 24 months of age;
- for solution for infusion;
- 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.

1.2. Condition: treatment of idiopathic thrombocytopenic purpura (ITP)

Idiopathic thrombocytopenic purpura (ITP) as model for immunomodulation effect.

This covers:

- idiopathic thrombocytopenic purpura, in children or adults at high risk of bleeding prior to surgery to correct the platelet count;
- Guillain Barré syndrome;
- Kawasaki disease;
- Allogeneic bone marrow transplantation.

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for solution for infusion.
- 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.

2. Paediatric Investigation Plan

2.1. Condition: treatment of primary immunodeficiency (PID)

2.1.1. Indication(s) targeted by the PIP

Treatment of primary immunodeficiency (PID).

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

From 2 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for infusion.

2.1.4. Measures

Area	Number of measures	Description
Quality related studies		Not applicable.
Non-clinical studies		Not applicable.
Clinical studies	1	**Study 1** A Multinational, multicentre, interventional, prospective, non- Randomized, open-Label, uncontrolled, single Group Assignment Study to Evaluate the Efficacy, Safety and Pharmacokinetics of human normal immunoglobulin 10% (I10E) in Patients with Primary Immunodeficiency (PID).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2013
Deferral for one or more studies contained in the paediatric investigation plan:	No