EMA/261382/2010

# European Medicines Agency decision

P/77/2010

of 7 May 2010

on the acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (EMEA-000167-PIP01-07-M01) 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 European Medicines Agency's decision P/115/2008 issued on 1 December 2008,

Having regard to the application submitted by LFB Biotechnologies on 23 December 2009 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 March 2010, 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 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. 50052 - Les Ulis, 91942 Courtaboeuf, France.

Done at London, 7 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/149771/2010

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

EMEA-000167-PIP01-07-M01

## Scope of the application

**Active substance(s):**

Human normal immunoglobulin

**Condition(s):**

Primary immunodeficiency (PID)

Idiopathic thrombocytopenic purpura (ITP)

Neonatal haemolytic disease (ABO - Rh-incompatability)

**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 23 December 2009 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/115/2008 of 1 December 2008. The application for modification proposed changes.

The procedure started on 21 January 2010.

## Scope of the modification

Some measures and timelines of the original opinion 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 the changes proposed by the applicant regarding the measures of the paediatric investigation plan

   The Norwegian Paediatric Committee member(s) agree(s) 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(es) and appendix.

London, 19 March 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)

Primary immunodeficiency (PID)

Idiopathic thrombocytopenic purpura (ITP)

Neonatal haemolytic disease (ABO - Rh-incompatibility).

# 2. Waiver

## *2.1. Condition*

1) 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 18 years of age for the solution for infusion for intravenous use,
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit.

2) Idiopathic thrombocytopenic purpura (ITP) as model for immunomodulation
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 the solution for infusion for intravenous use,
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit.

3) Neonatal haemolytic disease (ABO - Rh-incompatability).
The waiver applies to:

- Infants and toddlers (from 28 days to less than 24 months), Children (from 2 to less than 12 years), Adolescents (from 12 to less than 18 years)
- for the solution for infusion for intravenous 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).

# 3. Paediatric Investigation Plan

## *3.1. Condition to be investigated*

Neonatal haemolytic disease (ABO - Rh-incompatability).

### 3.1.1. Indication targeted by the PIP

Treatment of neonatal haemolytic disease (ABO - Rh-incompatability).

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

From birth to less than 28 days of age.

### 3.1.3. Pharmaceutical form(s)

Human normal immunoglobulin Solution for infusion for intravenous use 5g/100 ml (5%)

### 3.1.4. Studies

| **Area** | **Number of studies** | **Description** |
|---|---|---|
| Quality | | Not applicable. |
| Non-clinical | | Not applicable. |
| Clinical | 1 | Study 1)<br>Systematic review of the literature and perform a meta-analysis of all existing trials focusing on the efficacy and safety. |

# 4. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use: | **Yes** |
| Date of completion of the paediatric investigation plan: | By November 2009 |
| Deferral for one or more studies contained in the paediatric investigation plan: | No |