European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 7 September 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a waiver for human normal immunoglobulin (EMEA-000558-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 LFB Biotechnologies on 6 May 2009 under Article 16(1) of Regulation (EC) No 1901/2006 as amended 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 24 July 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

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 human normal immunoglobulin, 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 waiver for human normal immunoglobulin, 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

This decision is addressed to LFB Biotechnologies, 3 avenue des Tropiques - B.P. 50052 - Les Ulis, 91942 Courtaboeuf Cedex, France.

Done at London, 7 September 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/318992/2009
EMEA-000558-PIP01-09

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A WAIVER

Scope of the application

Active substance(s):
Human normal immunoglobulin

Condition(s):
Primary immunodeficiency (PID)
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 16(1) of Regulation (EC) No 1901/2006 as amended, LFB Biotechnologies submitted for agreement to the EMEA on 6 May 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 28 May 2009.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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 Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, 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 members 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 Agency, together with its annex(es) and appendix.

London, 24 July 2009

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

A. CONDITION(S)

1) Primary immunodeficiency (PID)

2) Idiopathic thrombocytopenic purpura (ITP)

B. WAIVER

- **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 24 months 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 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 the solution for infusion for intravenous use on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Primary immunodeficiency (PID) as model for replacement therapy

- **Proposed PIP indication**

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 24 months to less than 18 years.

- **Formulation(s)**

  Human normal immunoglobulin Solution for infusion for intravenous use 100 mg/100 ml (10%)

- **Studies**

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	1	A Multinational, Multicentre, Interventional, Prospective, Non-Randomized, Open-Label, Uncontrolled, Single Group Assignment Study to Evaluate the Tolerability, Safety and Pharmacokinetics of IGNG 10% in Patients With Primary Immunodeficiency (PID)

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By June 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**