EMA/954001/2011

European Medicines Agency decision

P/308/2011

of 20 December 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the refusal of a waiver for chimeric monoclonal anti-Shiga toxin (Stx) antibodies cαStx1 and cαStx2 (EMEA-001134-PIP01-11) 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 LFB Biotechnologies on 14 March 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation 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 11 November 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and 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 refusal 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 refusing 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 chimeric monoclonal anti-Shiga toxin (Stx) antibodies caStx1 and caStx2, solution for injection, 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 chimeric monoclonal anti-Shiga toxin (Stx) antibodies caStx1 and caStx2, solution for injection, 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 chimeric monoclonal anti-Shiga toxin (Stx) antibodies caStx1 and caStx2, solution for injection, 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 refused.

Article 4

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

Done at London, 20 December 2011

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

EMA/PDCO/757240/2011

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

EMEA-001134-PIP01-11

Scope of the application

Active substance(s):

Chimeric monoclonal anti-Shiga toxin (Stx) antibodies cαStx1 and cαStx2

Condition(s):

Prevention of Shiga toxin-mediated complications

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

LFB Biotechnologies

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, LFB Biotechnologies submitted for agreement to the European Medicines Agency on 14 March 2011 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 20 April 2011.

Supplementary information was provided by the applicant on 25 August 2011. The applicant proposed modifications to the paediatric investigation plan and requested a deferral.

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 in accordance with Article 21 of said Regulation,
    - to refuse the granting of a waiver in accordance with Article 13 of said Regulation, for some of the subsets of the paediatric population and the above mentioned condition(s) as it does not meet the grounds detailed in Article 11(1) of said Regulation.

The Icelandic and the Norwegian Paediatric Committee member(s) agree(s) with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan 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, 11 November 2011

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

The waiver is refused for the following:

1.1. Condition: Prevention of Shiga toxin-mediated complications

The request for the waiver applied to:

- the paediatric population from birth to less than 3 months of age;
- for solution for injection, intravenous use.

The waiver request does not provide evidence to support the following grounds set out in Article 11(1)b of Regulation (EC) No 1901/2006 that:

(b) the disease or condition for which the specific medicinal product is intended occurs only in adult populations;

because:

the disease or condition, for which the specific medicinal product is intended, does occur in the paediatric population(s) in all age groups.

The waiver request is therefore refused by the PDCO.

2. Paediatric Investigation Plan

2.1. Condition: Prevention of Shiga toxin-mediated complications

2.1.1. Indication(s) targeted by the PIP

Prevention of Shiga toxin-mediated complications resulting from Shiga toxin producing bacterial infections.

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	**Study 1** Double blind, randomised, multicentre, single dose, three arm, placebo-controlled trial to evaluate the safety and tolerability of two doses of Chimeric Monoclonal Antibodies to Shiga Toxins 1 (cαStx1) and 2 (cαStx2) in children from 6 months to less than 18 years with early signs of Shiga toxin producing bacterial infection, with 12 months open-label extension to evaluate safety. **Study 2** Double blind, randomised, multicentre, single dose, placebo-controlled trial to evaluate the efficacy of Chimeric Monoclonal Antibodies to Shiga Toxins 1 (cαStx1) and 2 (cαStx2) in children from birth to less than 18 years with watery diarrhoea, caused by Shiga toxin-producing bacterial infection, with 12 months open-label extension to evaluate long-term efficacy and safety.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes