EMA/306450/2013

European Medicines Agency decision

P/0142/2013

of 3 July 2013

on the acceptance of a modification of an agreed paediatric investigation plan for icatibant acetate (Firazyr), (EMEA-000408-PIP01-08-M04) 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 icatibant acetate (Firazyr), (EMEA-000408-PIP01-08-M04) 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/222/2009 issued on 4 November 2009, the decision P/72/2010 issued on 5 May 2010, and the decision P/238/2011 issued on 30 September 2011,

Having regard to the application submitted by Shire Orphan Therapies GmbH on 22 February 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 May 2013, in accordance with Article 22 of Regulation (EC) No 1901/2006, and Article 21 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 acceptance of changes to the agreed paediatric investigation plan and on the granting of a deferral.

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

(3) It is therefore appropriate to adopt a decision on the granting of a deferral.

[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 icatibant acetate (Firazyr), solution for injection in pre-filled syringe, subcutaneous 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

A deferral for icatibant acetate (Firazyr), solution for injection in pre-filled syringe, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Shire Orphan Therapies GmbH, Friedrichstrasse 149, 10117 – Berlin, Germany.

Done at London, 3 July 2013

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

EMA/PDCO/123948/2013

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

EMEA-000408-PIP01-08-M04

Scope of the application

Active substance(s):

Icatibant acetate

Invented name:

Firazyr

Condition(s):

Treatment of hereditary angioedema (HAE)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection in pre-filled syringe

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Shire Orphan Therapies GmbH

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Shire Orphan Therapies GmbH submitted to the European Medicines Agency on 22 February 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/222/2009 issued on 4 November 2009, the decision P/72/2010 issued on 5 May 2010, and the decision P/238/2011 issued on 30 September 2011.

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

The procedure started on 20 March 2013.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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;
   - to grant a deferral, the details of which are 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 subsets of the paediatric population and condition 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 annexes and appendix.

London, 17 May 2013

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

1.1. Condition: treatment of hereditary angioedema

The waiver applies to:

- Neonates, infants and toddlers from birth to less than 2 years of age;
- for solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric Investigation Plan

2.1. Condition: treatment of hereditary angioedema

2.1.1. Indication(s) targeted by the PIP

Symptomatic treatment of acute attacks of hereditary angioedema associated with C1 esterase inhibitor deficiency.

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 injection in pre-filled syringe.

2.1.4. Measures

Area	Number of measures	Description
Quality		Not applicable.
Non-clinical	2	**Measure 1:** Local tolerance study in juvenile rats. **Measure 2:** 7-week toxicity study in juvenile rats with assessment of fertility before and after recovery.

Area	Number of measures	Description
Clinical	2	**Measure 3:** Double-blind, randomized, placebo-controlled study to assess the effect of icatibant on serum reproductive hormone levels after repeated administration of three subcutaneous doses. (JE049-1105). **Measure 4:** Open-label, non-randomized single-arm study to assess the pharmacokinetics, tolerability, and safety of a single subcutaneous administration of icatibant in children and adolescents with hereditary angioedema (JE049-2104).

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 2017
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Hereditary angioedema (HAE)

   Authorised indication(s):

   - Firazyr is indicated for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1-esterase-inhibitor deficiency).

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous use