EMA/624869/2015

# European Medicines Agency decision

P/0243/2015

of 30 October 2015

on the acceptance of a modification of an agreed paediatric investigation plan for icatibant acetate (Firazyr), (EMEA-000408-PIP01-08-M05) 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.**

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Contact EMA** www.ema.europa.eu/contact

# European Medicines Agency decision

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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/222/2009 issued on 4 November 2009, the decision P/72/2010 issued on 5 May 2010, the decision P/238/2011 issued on 30 September 2011 and the decision P/0142/2013 issued on 3 July 2013,

Having regard to the application submitted by Shire Orphan Therapies GmbH on 18 June 2015 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 11 September 2015, 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 icatibant acetate (Firazyr), solution for injection, 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***

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

Done at London, 30 October 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/417999/2015
London, 11 September 2015

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

EMEA-000408-PIP01-08-M05

## 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

**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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
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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 18 June 2015 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/222/2009 issued on 4 November 2009, the decision P/72/2010 issued on 5 May 2010, the decision P/238/2011 issued on 30 September 2011, and the decision P/0142/2013 issued on 3 July 2013.

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

The procedure started on 14 July 2015.

## 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.

   The Norwegian Paediatric Committee member agrees 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 annexes and appendix.

# 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 (PIP)

# 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

### 2.1.4. Measures

| Area | Number of measures | Description |
|---|---|---|
| Quality-related studies | 0 | Not applicable. |
| Non-clinical studies | 2 | **Study 1:**<br>Local tolerance study in juvenile rats.<br>**Study 2:**<br>7-week toxicity study in juvenile rats with assessment of fertility before and after recovery. |

| | | |
|---|---|---|
| Clinical studies | 2 | **Study 3:**<br>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).<br>**Study 4:**<br>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 (HGT-FIR-086). |
| Extrapolation, modelling and simulation studies | 0 | Not applicable. |
| Other studies | 0 | Not applicable. |
| Other measures | 0 | Not applicable. |

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

| | |
|---|---|
| Concerns on potential long term safety/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