EMA/249207/2010

European Medicines Agency decision

P/72/2010

of 5 May 2010

on the acceptance of a modification of an agreed paediatric investigation plan for icatibant acetate (Firazyr) (EMEA-000408-PIP01-08-M02) 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/222/2009 issued on 4 November 2009,

Having regard to the application submitted by Jerini AG on 5 February 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with 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 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 Jerini AG, Invalidenstr 130, 10115 – Berlin, Germany.

Done at London, 5 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/160540/2010

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

EMEA-000408-PIP01-08-M02

Scope of the application

Active substance(s):

Icatibant (acetate)

Invented name:

Firazyr

Condition(s):

Hereditary angioedema (HAE)

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Jerini AG

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Jerini AG submitted to the European Medicines Agency on 5 February 2010 an application for modification of the agreed paediatric investigation plan and a waiver as set out in the European Medicines Agency's decision P/222/2009 of 4 November 2009. The application for modification proposed changes.

The procedure started on 18 February 2010.

Scope of the modification

The request of modification regards change and clarification in dosing for women in study 1105.

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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 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.

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)

Hereditary angioedema

2. Waiver

2.1. Condition

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.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Hereditary angioedema

3.1.1. Indication targeted by the PIP

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

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

From 2 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Solution for injection

3.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical	**2**	• Subcutaneous administration local tolerance study in juvenile rats • 7-week toxicity study in juvenile rats with assessment of fertility before and after recovery
Clinical	**2**	• 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) • 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)

4. Follow-up, completion and deferral of PIP

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 December 2012
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

EU Number	Invented name Name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/08/461/001	Firazyr	30 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	3 ml (10 mg/ml)	1 pre-filled syringe + 1 needle