EMA/759834/2015

European Medicines Agency decision

P/0305/2015

of 21 January 2015

on the acceptance of a modification of an agreed paediatric investigation plan for lorcaserin (EMEA-001098-PIP01-10-M01) 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

P/0305/2015

of 21 January 2015

on the acceptance of a modification of an agreed paediatric investigation plan for lorcaserin (EMEA-001098-PIP01-10-M01) 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/243/2011 issued on 30 September 2011,

Having regard to the application submitted by Eisai Limited UK on 21 August 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 13 November 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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 lorcaserin, tablet, age-appropriate formulation, oral use, including changes to the deferral, 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 Eisai Limited UK, European Knowledge Centre, Mosquito Way, AL10 9SN – Hatfield, United Kingdom.

Done at London, 21 January 2015

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

EMA/PDCO/572417/2015
London, 13 November 2015

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

EMEA-001098-PIP01-10-M01

Scope of the application

Active substance(s):

Lorcaserin

Condition(s):

Treatment of obesity

Pharmaceutical form(s):

Tablet

Age-appropriate formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eisai Limited UK

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eisai Limited UK submitted to the European Medicines Agency on 21 August 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/243/2011 issued on 30 September 2011.

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

The procedure started on 15 September 2015.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

Scope of the modification

Some timelines 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 and to the deferral 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 annex 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 obesity

The waiver applies to:

- The paediatric population from birth to less than 2 years of age;
- for tablet, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

The waiver applies to:

- The paediatric population from 2 to less than 6 years of age;
- for tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of obesity

2.1.1. Indication(s) targeted by the PIP

Treatment of obesity

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

From 6 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

- Tablet
- Age-appropriate formulation to be developed for the paediatric subset from 6 to less than 12 years of age (flavoured liquid formulation, chewable tablet or orally disintegrating form).

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1:** Age-appropriate formulation to be developed for the paediatric subset from 6 to less than 12 years of age (flavoured liquid formulation, chewable tablet or orally disintegrating form).
Non-clinical studies	1	**Study 2:** 42-day toxicity study in juvenile rats, followed by a 4-week recovery period.
Clinical studies	4	**Study 3:** Open-label, uncontrolled, single dose study to evaluate pharmacokinetic parameters and safety of lorcaserin in obese post-pubertal children from Tanner stage equal or above 2 to less than 18 years of age. **Study 4:** Double-blind, randomised, multicentre, placebo-controlled trial to assess the safety and efficacy of lorcaserin in conjunction with lifestyle modifications for weight loss in obese post-pubertal children from Tanner stage equal or above 2 to less than 18 years of age, who have previously failed to respond to lifestyle modification measures alone. **Study 5:** Open-label, placebo-controlled, single ascending dose study of the safety, tolerability and pharmacokinetics of lorcaserin in obese pre-pubertal children from 6 years old to a Tanner stage 1. **Study 6:** Double-blind, randomised, multicentre, placebo-controlled trial to assess the safety and efficacy of lorcaserin in conjunction with lifestyle modifications for weight loss in obese pre-pubertal children from 6 years old to a Tanner stage 1, who have previously failed to respond to lifestyle modification measures alone.
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 and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By January 2031
Deferral for one or more studies contained in the paediatric investigation plan:	Yes