EMA/249393/2016

European Medicines Agency decision

P/0116/2016

of 22 April 2016

on the acceptance of a modification of an agreed paediatric investigation plan for rufinamide (Inovelon), (EMEA-000709-PIP01-09-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.

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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/153/2010 issued on 27 August 2010, the decision P/0275/2013 issued on 30 October 2013, the decision P/0277/2014 issued on 28 October 2014, the decision P/0263/2015 issued on 30 October 2015, and the decision P/0038/2016 issued on 19 February 2016,

Having regard to the application submitted by Eisai Limited on 23 March 2016 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 1 April 2016, 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 rufinamide (Inovelon), tablet, oral suspension, oral 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 Eisai Limited, European Knowledge Centre, Mosquito Way, AL10 9SN - Hatfield, Hertfordshire, United Kingdom.

Done at London, 22 April 2016

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

EMA/PDCO/228224/2016
London, 1 April 2016

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

EMEA-000709-PIP01-09-M05

Scope of the application

Active substance(s):

Rufinamide

Invented name:

Inovelon

Condition(s):

Treatment of Lennox-Gastaut Syndrome

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eisai Limited

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, Eisai Limited submitted to the European Medicines Agency on 23 March 2016 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/153/2010 issued on 27 August 2010, the decision P/0275/2013 issued on 30 October 2013, the decision P/0277/2014 issued on 28 October 2014, the decision P/0263/2015 issued on 30 October 2015, and the decision P/0038/2016 issued on 19 February 2016.

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

The procedure started on 30 March 2016.

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 Lennox-Gastaut syndrome

The waiver applies to:

- all subsets of the paediatric population from birth to less than 12 months of age;
- for oral suspension, 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(s);

and to:

- all subsets of the paediatric population from 4 to less than 18 years of age;
- for oral suspension and tablets, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of Lennox-Gastaut syndrome

2.1.1. Indication(s) targeted by the PIP

Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome

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

From 1 to less than 4 years of age

2.1.3. Pharmaceutical form(s)

Oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Palatability and acceptability assessment of the oral suspension in children with Lennox-Gastaut syndrome

Non-clinical studies	1	**Study 2** 14-week oral toxicity Study in juvenile dogs (901629)
Clinical studies	1	**Study 3** Multicentre, randomised, controlled, open-label study to evaluate the effect on cognitive development, safety, and pharmacokinetics of adjunctive rufinamide treatment in paediatric subjects 1 to less than 4 years of age with inadequately controlled Lennox-Gastaut syndrome

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Treatment of Lennox-Gastaut Syndrome

Authorised indication(s):

- adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 4 years of age and older

Authorised pharmaceutical form(s)

Film-coated tablet, oral suspension

Authorised route(s) of administration

Oral route