EMA/781916/2015

European Medicines Agency decision

P/0315/2015

of 21 December 2015

on the agreement of a paediatric investigation plan and on the granting of a waiver for ethosuximide (EMEA-001617-PIP01-14) 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 application submitted by Advicenne Pharma on 16 March 2015 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 November 2015, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 13 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 agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for ethosuximide, age-appropriate oral solid formulation, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A waiver for ethosuximide, age-appropriate oral solid formulation, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Advicenne Pharma, 2 rue Briçonnet, 30000 – Nîmes, France.

Done at London, 21 December 2015

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

EMA/PDCO/577234/2015
London, 13 November 2015

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMEA-001617-PIP01-14

Scope of the application

Active substance(s):

Ethosuximide

Condition(s):

Treatment of childhood absence epilepsy

Pharmaceutical form(s):

Age-appropriate oral solid formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Advicenne Pharma

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Advicenne Pharma submitted for agreement to the European Medicines Agency on 16 March 2015 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 21 April 2015.

Supplementary information was provided by the applicant on 24 August 2015. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. 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 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 childhood absence epilepsy

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- age-appropriate oral solid formulation, 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).

2. Paediatric investigation plan

2.1. Condition:

Treatment of childhood absence epilepsy

2.1.1. Indication(s) targeted by the PIP

Treatment of childhood absence epilepsy

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)

Age-appropriate oral solid formulation

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	***Study 1*** Development of an age-appropriate solid formulation such as granules for use in the paediatric population from 2 to less than 18 years.
Non-clinical studies	0	Not applicable.

Area	Number of measures	Description
Clinical studies	3	***Study 2*** A randomised controlled, 3-way crossover, partially-blind study in healthy subjects to investigate pharmacokinetics, pharmacodynamics, palatability, safety and tolerability of ADV6770 as novel ethosuximide oral formulation versus placebo and the marketed syrup. (A01CS) ***Study 3*** Randomised, controlled, 3-period, single dose cross-over, open-label study in healthy subjects to evaluate pharmacokinetics, safety and tolerability of ADV6770 ethosuximide novel oral formulation versus the marketed syrup and the marketed capsules. (A02CS) ***Study 4*** A Phase IIb randomised, active controlled, open-label, 2-way cross-over multicentre study to investigate palatability, acceptability, pharmacokinetics, pharmacodynamics, safety and tolerability and treatment compliance of multidoses of ADV6770 as monotherapy or in combination, in children with childhood absence epilepsy.(A11CS)
Extrapolation, modelling and simulation studies	1	***Study 5*** Population PK evaluation based on ethosuximide concentration levels at different time points and the individual information about the subjects (demographic and biological characteristics).(A12MS)
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:	No
Date of completion of the paediatric investigation plan:	By June 2017
Deferral for one or more measures contained in the paediatric investigation plan:	No