



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/317063/2013

European Medicines Agency decision

P/0132/2013

of 31 May 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral for lacosamide (Vimpat) (EMA-000402-PIP02-11) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by UCB Pharma S.A. on 7 November 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 April 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 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 deferral.
- (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 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

A paediatric investigation plan for lacosamide (Vimpat), film-coated tablet, syrup, solution for infusion, oral use, intravenous 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 deferral for lacosamide (Vimpat), film-coated tablet, syrup, solution for infusion, oral use, intravenous 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 UCB Pharma S.A., Allée de la Recherche 60, 1070 Brussels, Belgium.

Done at London, 31 May 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)



EUROPEAN MEDICINES AGENCY
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EMA/PDCO/136431/2013 Corr

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

EMA-000402-PIP02-11

Scope of the application

Active substance(s):

Lacosamide

Invented name:

Vimpat

Condition(s):

Treatment of epilepsy with partial onset seizures

Treatment of generalised epilepsy and epileptic syndromes

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Syrup

Solution for infusion

Route(s) of administration:

Oral use

Intravenous use

Name / corporate name of the PIP applicant:

UCB Pharma S.A.

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, UCB Pharma S.A. submitted for agreement to the European Medicines Agency on 7 November 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 14 December 2011.

Supplementary information was provided by the applicant on 18 January 2013. 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 deferral in accordance with Article 21 of said Regulation.

The Icelandic and the Norwegian Paediatric Committee members agree 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 annexes and appendix.

London, 12 April 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

Not applicable

2. Paediatric Investigation Plan

2.1. Condition: Treatment of epilepsy with partial onset seizures

2.1.1. Indication(s) targeted by the PIP

Treatment of epilepsy with partial onset seizures.

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablet.

Syrup.

Solution for infusion.

2.1.4. Measures

Area	Number of measures	Description
Quality	3	Measure 1 Confirmation of the age-appropriateness of the current commercial lacosamide film-coated tablets (for oral use) for the target population. Measure 2 Confirmation of the age-appropriateness of the current commercial lacosamide solution for infusion (for intravenous use) for the target population. Measure 3 Confirmation of the age-appropriateness of the current commercial lacosamide syrup (for oral use) for the target population.
Clinical	14	Measure 4 PBPK prediction of oral lacosamide pharmacokinetics and dose adaptations in children from birth to less than 18 years (CL0096). Measure 5 Population pharmacokinetics of lacosamide in children with partial onset seizures aged from 1 month to less than 18 years, based in data from studies

Area	Number of measures	Description
		SP847 and SP1047. Measure 6 Physiologically based pharmacokinetic (PBPK) prediction of intravenous lacosamide pharmacokinetics and dose adaptations in neonates (aged from birth to 28 days). Measure 7 Predictive population pharmacokinetics of intravenous lacosamide in children from birth to less than 18 years. Measure 8 Final retrospective population pharmacokinetics model of lacosamide in children from birth to less than 18 years, combining all available data at the end of the program. Measure 9 Exposure-response modelling of oral lacosamide in adjunctive treatment of children with POS, using the data from the Phase 3 studies SP0967 (1 month to less than 4 years of age) and SP0969 (4 years to less than 18 years). Measure 10 Bridging PK and PK/PD simulations to determine paediatric dose adaptation rules for POS monotherapy with lacosamide in children aged 1 month to less than 18 years. Measure 11 Open-label safety and pharmacokinetic adjunctive treatment study in paediatric subjects from 1 month to less than 18 years of age with partial-onset seizures (SP847). Measure 12 Open-label, multicentre study to investigate the pharmacokinetics (PK) of lacosamide (commercially available tablet or oral solution) as therapy in children (aged from 1 month to less than 18 years) who are prescribed lacosamide for epilepsy (SP1047). Measure 13 Double blind, randomised, parallel group, placebo controlled adjunctive treatment study of lacosamide in children with partial-onset seizures aged from 1 month to less than 4 years to evaluate safety, tolerability and pharmacokinetics (SP0967). Measure 15 Open-label, multi-centre, parallel-group, non-inferiority efficacy, safety and tolerability study for adjunctive lacosamide treatment of neonatal seizures in

Area	Number of measures	Description
		term neonates (SP0968). Measure 16 Open-label, active controlled study comparing the safety of lacosamide as monotherapy in children from 1 month to less than 18 years of age with partial-onset seizures with or without secondarily generalized seizures (SP0XXX). Measure 18 Open label, long term safety, tolerability and pharmacokinetic study in children from birth to less than 18 years with epilepsy; extension study for subjects from SP847, SP0966, and SP0968 (SP848). Measure 19 Open-label long-term extension study in children from 1 month to less than 18 years with partial-onset seizures to evaluate safety, tolerability, effects on behaviour, cognition and quality of life (EP0034).

2.2. Condition: Treatment of generalised epilepsy and epileptic syndromes

2.2.1. Indication(s) targeted by the PIP

Treatment of generalised epilepsy and epileptic syndromes.

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

From birth to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Film-coated tablet.

Solution for infusion.

Syrup.

2.2.4. Measures

Area	Number of measures	Description
Quality	3	Measure 1 As described for condition 'Treatment of epilepsy with partial onset seizures'. Measure 2 As described for condition 'Treatment of epilepsy with partial onset seizures'. Measure 3 As described for condition 'Treatment of epilepsy with partial onset seizures'.
Clinical	12	Measure 4 As described for condition 'Treatment of epilepsy with partial onset seizures'. Measure 5 As described for condition 'Treatment of epilepsy with partial onset seizures'. Measure 6 As described for condition 'Treatment of epilepsy with partial onset seizures'. Measure 7 As described for condition 'Treatment of epilepsy with partial onset seizures'. Measure 8 As described for condition 'Treatment of epilepsy with partial onset seizures'. Measure 12 As described for condition 'Treatment of epilepsy with partial onset seizures'. Measure 14 Exploratory, open-label, study in paediatric subjects from 1 month to less than 18 years for safety and tolerability and preliminary efficacy for adjunctive lacosamide treatment of epilepsy syndromes associated with generalized epilepsy excluding primary generalised tonic clonic seizures with Idiopathic Generalised Epilepsy (SP0966). Measure 15 As described for condition 'Treatment of epilepsy with partial onset seizures'. Measure 17 Double-blind, randomized, placebo-controlled study in children from 1 month to less than 18 years with generalized epilepsy excluding primary generalised tonic clonic seizures with idiopathic generalised epilepsy (syndrome to be determined based on results of SP0966) (SP0YYY). Measure 18

Area	Number of measures	Description
		As described for condition 'Treatment of epilepsy with partial onset seizures'. Measure 20 Double-blind, randomised, placebo-controlled, parallel group, multi-centre study to evaluate efficacy and safety of lacosamide as adjunctive treatment for uncontrolled primary generalized tonic-clonic (PGTC) seizures in subjects aged 4 years and above with idiopathic generalized epilepsy (IGE) (SP0982). Measure 21 Open-label, multi-centre, extension study to evaluate safety and tolerability of lacosamide as adjunctive treatment for idiopathic generalized epilepsy (IGE) with uncontrolled primary generalized tonic-clonic (PGTC) seizures in subjects aged 4 years and above with idiopathic generalized epilepsy (IGE) (EP0012).

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 December 2022
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. Treatment of epilepsy with partial-onset seizures.

Authorised indication(s):

- Vimpat is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy.

Authorised pharmaceutical form(s):

Film-coated tablet, syrup, solution for infusion.

Authorised route(s) of administration:

Oral use, intravenous use.