

EMA/439683/2021

European Medicines Agency decision P/0349/2021

of 20 August 2021

on the acceptance of a modification of an agreed paediatric investigation plan for lacosamide (Vimpat), (EMA-000402-PIP03-17-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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on the acceptance of a modification of an agreed paediatric investigation plan for lacosamide (Vimpat), (EMA-000402-PIP03-17-M05) 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 726/2004¹,

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 European Medicines Agency's decision P/0153/2017 issued on 2 June 2017, the decision P/0336/2017 issued on 30 October 2017, the decision P/0048/2018 issued on 22 February 2018, the decision P/0059/2019 issued on 28 February 2019 and the decision P/0330/2020 issued on 21 August 2020,

Having regard to the application submitted by UCB Pharma S.A. on 16 April 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 July 2021, 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 lacosamide (Vimpat), film-coated tablet, syrup, solution for infusion, oral use, intravenous 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0132/2013 issued on 13/5/2013, including subsequent modifications thereof.

Article 3

This decision is addressed to UCB Pharma S.A., 60 Allée de la Recherche, 1070 – Brussels, Belgium.

EMA/PDCO/242947/2021
Amsterdam, 23 July 2021

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000402-PIP03-17-M05

Scope of the application

Active substance(s):

Lacosamide

Invented name:

Vimpat

Condition(s):

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 22 of Regulation (EC) No 1901/2006 as amended, UCB Pharma S.A. submitted to the European Medicines Agency on 16 April 2021 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0153/2017 issued on 2 June 2017, the decision P/0336/2017 issued on 30 October 2017, the decision P/0048/2018 issued on 22 February 2018, the decision P/0059/2019 issued on 28 February 2019 and the decision P/0330/2020 issued on 21 August 2020.

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

The procedure started on 25 May 2021.

Scope of the modification

Some measures and 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 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 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

Not applicable

2. Paediatric Investigation Plan

2.1. Condition

Treatment of generalised epilepsy and epileptic syndromes

2.1.1. Indication(s) targeted by the PIP

Treatment of generalised epilepsy and epileptic syndromes

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

Solution for infusion

Syrup

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	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 studies	6	Study 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).

		Study 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 seizures excluding primary generalised tonic clonic seizures with Idiopathic Generalised Epilepsy and excluding typical absence (Type IIA1) or atypical absence (Type IIA2) seizures when occurring exclusively from other seizure types (SP0966). Study 15 Open-label, multi-centre, parallel-group, non-inferiority efficacy, safety, tolerability and PK study for adjunctive lacosamide treatment in neonates with repeated electroencephalographic neonatal seizures (SP0968). <i>Study 17: deleted during procedure EMEA-000402-PIP03-17-M03.</i> Study 18 Open label, long term safety, tolerability and pharmacokinetic study in children from 1 month to less than 18 years with epilepsy; extension study for subjects from other LCM studies including SP847 and SP0966 (SP848). Study 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). Study 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).
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Extrapolation, modelling and simulation studies	5	Study 4 PBPK prediction of oral lacosamide pharmacokinetics and dose adaptations in children from birth to less than 18 years (CL0096). Study 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 SP847 and SP1047. Study 6 Physiologically based pharmacokinetic (PBPK) prediction of intravenous lacosamide pharmacokinetics and dose adaptations in neonates (aged from birth to 28 days). Study 7 Predictive population pharmacokinetics of intravenous lacosamide in children from birth to less than 18 years. Study 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.
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:	Yes
Date of completion of the paediatric investigation plan:	By December 2024
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 monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy.

Authorised pharmaceutical form(s):

Film-coated tablet

Syrup

Solution for infusion

Authorised route(s) of administration:

Oral use

Intravenous use