MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100087-PIP01-21-M01

Scope of the Application

Active Substance(s)

LACOSAMIDE

Condition(s)

Treatment of generalised epilepsy and epileptic syndromes

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 Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, UCB Pharma Ltd. submitted to the licensing authority on 20/05/2021 14:16 BST an application for a Modification

The procedure started on 22/02/2022 14:36 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100087-PIP01-21-M01

Of 30/03/2022 08:27 BST

On the adopted decision for LACOSAMIDE (MHRA-100087-PIP01-21-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for LACOSAMIDE, Film-coated tablet, Syrup, Solution for infusion , Oral use, Intravenous use .

This decision is addressed to UCB Pharma Ltd., 208 Bath Road, Slough, United Kingdom, SL1 3WE

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of generalised epilepsy and epileptic syndromes

2.2 Indication(s) targeted by the PIP:

Treatment of generalised epilepsy and epileptic syndromes

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet; Syrup; Solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	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.
Non-Clinical Studies	0	Not applicable
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 generalised 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 and tolerability study for adjunctive lacosamide treatment of

		neonatal seizures in term neonates (SP0968). Study 17: deleted during procedure EMEA-000402-PIP03-17-M03. 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 generalised tonic-clonic (PGTC) seizures in subjects aged 4 years and above with idiopathic generalised epilepsy (IGE) (SP0982). Study 21 Open-label, multi-centre, extension study to evaluate safety and tolerability of lacosamide as adjunctive treatment for idiopathic generalised epilepsy (IGE) with uncontrolled primary generalized tonic-clonic (PGTC) seizures in subjects aged 4 years and above with idiopathic generalised epilepsy (IGE) (EP0012).
Extrapolation, Modeling & 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 a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	31/12/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes