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Human Medicines Division

Assessment report for paediatric studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

Vimpat

Lacosamide

Procedure no: EMA/PAM/0000303848

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Status of this report and steps taken for the assessment				
Current step[1]	**Description**	**Planned date**	**Actual Date**	**Need for discussion[2]**
☐	Start of procedure	2025-12-01	2025-12-01	☐
☐	CHMP Rapporteur Assessment Report	2026-01-05	2025-12-11	☐
☐	CHMP members comments	2026-01-19	n/a	☐
☐	Updated CHMP Rapporteur Assessment Report	2026-01-22	n/a	☐
☒	CHMP adoption of conclusions:	2026-01-29	2026-01-29	☐

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1. Introduction

On 6 October 2025, the MAH submitted the final reports for the following studies, in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

- **SP0968** - A Multicentre, Open-Label, Randomized, Active Comparator Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Lacosamide in Neonates with Repeated Electroencephalographic Neonatal Seizures

- The associated final PK modelling report **CL0447, Part V** - update of CL0447-Part IV Population Pharmacokinetic Model for Lacosamide using Data from Study SP0968

A short critical expert overview has also been provided.

2. Scientific discussion

2.1. Information on the development program

The MAH stated that studies SP0968 and CL0047-Part V are part of a development program for use of lacosamide (LCM) in neonatal seizures. No changes to the Vimpat product information is requested as part of this Article 46 submission. Instead, a separate variation is planned to be submitted in the first half of 2026, upon the completion of the ongoing retrospective real-world evidence (RWE) study on long term neurodevelopmental outcomes (EP0223). This Type II variation will encompass a comprehensive package of all available data on lacosamide in neonates, in support of the proposed SmPC updates for Vimpat. A line listing of all the concerned studies is included in Table 1.

Table 1. ***Development program for use of lacosamide in neonatal seizures.***

Study	Brief description	Type	Study status/Article 46 submission
EP0147	Loading dose safety of IV LCM in neonates (<30 days) and paediatric patients ≥30 days to <17 years of age	RWE	Complete/complete
EP0148	AED treatment patterns in neonates (<30 days)	RWE	Complete/complete
EP0149	Retrospective chart review of safety and possible effectiveness of LCM for neonatal seizures (<44 weeks postmenstrual age)	RWE/ collaborative	Complete/complete
EP0155	Safety and EEG response to LCM for neonatal seizures (<30 days)	RWE	Complete/complete
SP0968	≥2nd line treatment in neonates	Clinical/PK	Complete/ongoing
CL0447-Part V	PK model dosage in neonates	PK modelling	Complete/ongoing
EP0223	Retrospective neurocognitive outcome study following LCM treatment in neonatal seizures (≤28 days)	RWE	Ongoing/planned

AED=antiepileptic drug; EEG=electroencephalogram; IV=intravenous; LCM=lacosamide; PK=pharmacokinetic(s); RWE=real-world evidence

2.2. Information on the pharmaceutical formulation used in the studies

The study treatments and arm assignments for study SP0968 are outlined in Table 2.

Table 2. ***Treatments administered***

Treatment name	**LCM**		**Active Comparator**
Dose formulation	IV for infusion [a]	Oral solution [b]	Based on local practice and treatment guidelines
Unit dose strength(s)	10mg/mL		
Dosage level(s) [c]	X [d] mg/kg, tid, infusion over 30 minutes	Y [d] mg/kg, bid, oral	
Route of administration	IV	oral	
Sourcing	Provided centrally by UCB		Provided by investigational site
Packaging and labelling	Packaged in glass vials	Packaged in amber bottles	Per manufacturer's label
	Clinical drug supplies were labelled in accordance with the current ICH guidelines on GCP and GMP and included any locally required statements. If necessary, labels were translated into the local language.		

bid=twice daily; GCP=Good Clinical Practice; GMP=Good Manufacturing Practice; ICH=International Council for Harmonisation; IRT=interactive response technology; IV=intravenous; LCM=lacosamide; tid=three times a day
[a] Administered during treatment period.
[b] Administered during extension period.
[c] For LCM dose, the rounding rules for weight to dose calculations was provided by IRT.
[d] The actual dose of LCM was provided by IRT.

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted final reports for:

- SP0968 - A Multicentre, Open-Label, Randomized, Active Comparator Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Lacosamide in Neonates with Repeated Electroencephalographic Neonatal Seizures.

- The associated final PK modelling report CL0447, Part V - update of CL0447-Part IV Population Pharmacokinetic Model for Lacosamide using Data from Study SP0968.

Lacosamide has been approved as monotherapy and adjunctive treatment in patients with partial-onset seizures (minimum age varying between 1 month and 18 years depending on individual country) and as adjunctive treatment of primary generalized tonic-clonic seizures in patients with idiopathic generalized epilepsy (minimum age of 4 years, depending on individual country). Lacosamide is approved for treatment of partial-onset seizures for patients ≥1 month of age in the United States. SP0968 represented the first clinical study of lacosamide in neonatal study participants.

2.3.2. Clinical studies

SP0968: A Multicenter, Open-Label, Randomized, Active Comparator Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Lacosamide in Neonates with Repeated Electroencephalographic Neonatal Seizures

Description

SP0968 was a Phase 2/3, multicentre, open-label, randomized, active comparator study that evaluated the PK, efficacy, safety, and tolerability of lacosamide in neonatal study participants (herein referred to as "study participants") with repeated electroencephalographic neonatal seizures (ENS) compared with an active comparator chosen based on standard of care per the local practice and treatment guidelines. Only those study participants who did not have adequate seizure control with previous antiepileptic drug (AED) treatment were permitted to enrol in SP0968. This parallel-group, noninferiority study evaluated the efficacy, safety, tolerability, and PK of adjunctive lacosamide treatments in neonates.

Methods

Study participants

The study enrolled participants ≥34 weeks of corrected gestational age (CGA), <46 weeks of CGA, and <28 days of postnatal age (PNA) at the time of signing the informed consent. The eligible participants must have had confirmation on video-EEG of ≥2 minutes of cumulative ENS or ≥3 identifiable ENS prior to entering the treatment period and must have received either phenobarbital, levetiracetam, or midazolam (in any combination) before entering the study. The study excluded participants who received treatment with phenytoin, lidocaine, or other sodium channel blockers at any time prior to randomisation. ENS was defined as a seizure lasting for at least 10 seconds on video-EEG, despite receiving previous AED treatment (phenobarbital, levetiracetam, or midazolam in any combination; additional benzodiazepines were allowed).

Randomisation and blinding (masking)

Following the baseline assessments, study participants were randomised 1:1 to either the lacosamide or active comparator (standard of care, based on local practice and treatment guidelines) treatment group; the randomization was stratified by seizure severity at baseline. The study was open-label.

Treatments

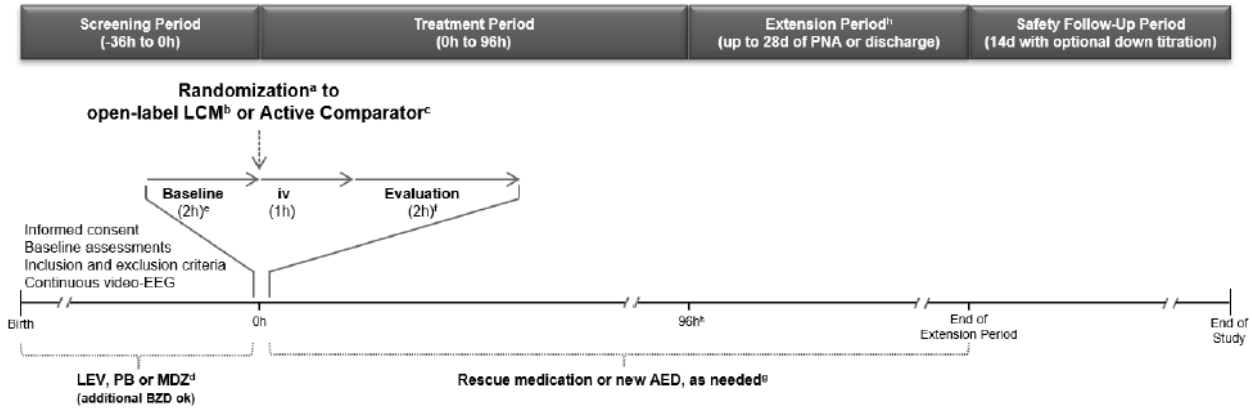
Study participants randomised to lacosamide received an IV infusion over 30 minutes. A dose of lacosamide of 15 mg/kg/day was estimated to yield approximately the same plasma concentrations as in an adult receiving LCM 400 mg/day, the maximum dose approved for adjunctive therapy in adults.

The total duration of the study for an individual study participant was a maximum of 42 days and consisted of the following defined periods:

- Screening Period: Up to 36 hours (-36 hours to 0 hour)
- Treatment Period: 96 hours (0 hour to 96 hours)
- Extension Period: Up to 28 days of PNA
- Safety Follow-up Period (with optional down titration): 14 days

The study schematic is presented in Figure 1.

Figure 1. ***Schematic overview of the study***



AED=antiepileptic drug; BDZ=benzodiazepine; d=day; ENS=electroencephalographic neonatal seizures; h=hour; IRT=Interactive Response Technology;
iv=intravenous; LCM=lacosamide; LEV=levetiracetam; MDZ=midazolam; PB=phenobarbital; PNA=postnatal age; SFU=Safety Follow-up; StOC=standard of
care; video-EEG=video-electroencephalogram
a Study participants eligible based on baseline video-EEG seizure burden and other inclusion and exclusion criteria were randomized to the LCM or active comparator treatment group.
b Study participants randomized to LCM received an IV infusion of LCM over 30 minutes, 3 times a day. The actual LCM dose during the study for each study participant was provided by IRT.
c Study participants randomized to active comparator received an active comparator treatment chosen and dosed based on StOC (per local practice and treatment guidelines).
d Study participants must have been administered LEV, PB, or MDZ (in any combination) for treatment of ENS prior to enrolment. Other BDZ may have been given additionally. Sodium channel blockers (such as phenytoin or lidocaine) were not permitted prior to enrolment but were permitted in the Active Comparator treatment group (i.e., the Active Comparator may have been a sodium channel blocker).
e Video-EEG recording may have been shortened per clinical need (e.g., if status epilepticus was detected). If possible, an attempt was made to record at least 30 minutes of Baseline video-EEG.
f Evaluation for efficacy started 1 hour after initiation of randomized treatment (LCM or Active Comparator) and was used for assessment of the primary endpoint based on video-EEG.
g Ideally, rescue medication was not to be given within the first 3 hours of randomized treatment; however, the administration of rescue medication was always at the discretion of the Investigator.
h Study participants who benefited from randomized treatment (LCM or Active Comparator) could continue to the Extension Period. Study participants who discontinued randomized treatment at any time (Treatment or Extension Period), completed the Extension Period, were discharged from the hospital, or reached 28 days PNA entered the 14-day SFU Period with optional down titration. Study participants returned to the site for the SFU Visit at the end of the 14-day SFU Period.

Objectives

The primary objective was to evaluate the efficacy of lacosamide versus an active comparator chosen based on standard of care in severe and non-severe seizure burden (defined as total minutes of ENS per hour) in neonates with seizures that were not adequately controlled with previous AED treatment.

There were several secondary objectives, including but not limited to: further evaluate the efficacy of lacosamide versus an active comparator in severe and non-severe seizure burden (defined as total minutes of ENS per hour) in neonates with seizures that were not adequately controlled with previous AED treatment; to evaluate the short-term safety and tolerability of lacosamide in neonates; and to evaluate the PK of lacosamide in neonates who had seizures that were not adequately controlled with previous AED treatment.

Outcomes/endpoints

The primary endpoint was the reduction in seizure burden measured in the evaluation video-EEG compared with the baseline video-EEG.

There were several secondary efficacy endpoints, including but not limited to: proportion of responders, proportion of participants with at least 80% reduction in seizure burden, time to response, time to seizure freedom, absolute and percent reduction in seizure burden, etc.

Safety endpoints included number of TEAEs as reported by the investigator and percentage of treatment-emergent marked abnormalities in 12-lead ECG. PK endpoint was the mean serum concentration of LCM.

Sample size

A total of 32 study participants were planned to be enrolled. The study ended prematurely due to infeasibility of enrolment of all planned study participants. At the premature completion of enrolment, 59 study participants were screened and 29 study participants were randomized, of whom 26 participants received at least 1 dose of study treatment, including 14 participants who received lacosamide and 12 participants who received active comparator.

Statistical Methods

The planned analyses, comparisons, and determination of sample size are described in the final version of the statistical analysis plan. Given the scarcity of prior evidence in randomised controlled studies in the chosen indication and line of treatment, SP0968 was considered exploratory with no formal sample size calculation.

Results

Participant flow

A summary of study participant disposition and discontinuation reasons is presented in Table 3. All 26 participants (100%) completed the 30 minutes of video-EEG, and 21 participants (80.8%) completed 48 hours of video-EEG, 12 participants (85.7%) in the lacosamide group and 9 participants (75.0%) in the active comparator group. The study treatments in the active comparator group included phenobarbital and fosphenytoin (5 participants [41.7%] each) and levetiracetam (2 participants [16.7%]).

Table 3. ***Summary of participant disposition and discontinuation reasons (safety set)***

Disposition	**Active Comparator (StOC) N=12 n (%)**	**Lacosamide N=14 n(%)**	**All participants N=26 n (%)**
Randomised	12 (100)	14 (100)	26 (100)
Entered treatment period [a]	12 (100)	14 (100)	26 (100)
Completed evaluation period [b]	12 (100)	14 (100)	26 (100)
Completed 30 minutes of video-EEG in evaluation period [c]	12 (100)	14 (100)	26 (100)
Completed 48 hours of video-EEG [d]	9 (75.0)	12 (85.7)	21 (80.8)
Attended SFU Visit	11 (91.7)	14 (100)	25 (96.2)
Completed study [e]	11 (91.7)	14 (100)	25 (96.2)
Discontinued	1 (8.3)	0	1 (3.8)
Primary reason for discontinuation			
Adverse event	0	0	0
Lack of efficacy	0	0	0
Protocol violation	0	0	0
Lost to follow up	0	0	0
Consent withdrawn	1 (8.3)	0	1 (3.8)
Other	0	0	0

eCRF=electronic case report form; SFU=safety follow-up; StOC=standard of care; video-EEG=video-electroencephalogram
a Entered the treatment period was defined as receiving at least 1 dose of study treatment.
b Completed the evaluation period was defined as completing 3 hours of video-EEG monitoring after the first administration of study treatment. For analysis purposes, this was defined as continuing video-EEG monitoring for at least 3 hours after the first dose of study treatment, regardless of interruptions.
c Completed 30 minutes of video-EEG in the evaluation period was defined as having at least 30 minutes of interpretable video-EEG data available between 1 and 3 hours after the first administration of study treatment.
d Completed 48 hours of video-EEG is defined as having at least 30 minutes of interpretable video-EEG data available for the analysis of the 48-hour time point.
e Completed the study is determined from the study termination eCRF.

Baseline data

A summary of study participant baseline characteristics is presented in Table 4.

Table 4. ***Baseline characteristics (safety set)***

Variable	Statistic	Active Comparator (StOC) N=12	Lacosamide N=14	All participants N=26
Apgar score (1 min after birth)	n	12	13	25
	Mean (SD)	5.5 (3.0)	4.6 (3.0)	5.0 (3.0)
	Median (min, max)	6.5 (0, 8)	4.0 (1, 9)	6.0 (0, 9)
Apgar score (5 min after birth)	n	12	13	25
	Mean (SD)	7.1 (3.3)	6.8 (2.3)	7.0 (2.8)
	Median (min, max)	9.0 (0, 9)	7.0 (3, 9)	9.0 (0, 9)
Apgar score (10 min after birth)	n	5	7	12
	Mean (SD)	5.8 (2.7)	5.9 (3.2)	5.8 (2.9)
	Median (min, max)	7.0 (3, 9)	6.0 (0, 9)	6.5 (0, 9)
Primary cause for seizures [a]				
HIE, haemorrhage or infarction [b]	n (%)	6 (50.0)	11 (78.6)	17 (65.4)
CNS malformations [c]	n (%)	0	1 (7.1)	1 (3.8)
CNS infections [d]	n (%)	0	0	0
Other [e]	n (%)	6 (50.0)	2 (14.3)	8 (30.8)
Seizure burden severity				
Severe	n (%)	4 (33.3)	6 (42.9)	10 (38.5)
Non-severe	n (%)	8 (66.7)	8 (57.1)	16 (61.5)
Concomitant hypothermia treatment				
Yes	n (%)	2 (16.7)	4 (28.6)	6 (23.1)
No	n (%)	10 (83.3)	10 (71.4)	20 (76.9)

CNS=central nervous system; eCRF=electronic case report form; HIE=hypoxic-ischemic encephalopathy; max=maximum; min=minimum; SD=standard deviation; StOC=standard of care
Note: Seizure burden severity was determined at baseline by the Investigator.
Note: The concomitant hypothermia treatment subgroup is defined as 'Yes' for all participants with any documented concomitant hypothermia treatment as per the dedicated eCRF page.
a Primary reason for seizure was based on the most recent assessment available at baseline.
b Included HIE, ischemic stroke, and intracranial haemorrhage.
c Included brain malformations.
d Included intracranial infections.
e Included epileptic encephalopathy/genetic epilepsy, inborn error of metabolism, undetermined causes, and other causes.

Efficacy results

The interpretation of efficacy results in SP0968 is limited by the small number of study participants; 15 participants in the lacosamide group and 9 in the active comparator groups. Therefore, the efficacy observations presented should be interpretated with caution. Since the study concluded earlier than expected and the final data were not normally distributed, the primary efficacy analysis was conducted using descriptive statistics. A summary of absolute reduction in seizure burden from baseline in the evaluation period (1 to 3 hours) is presented for the full analysis set in Table 5.

Table 5. ***Reduction in seizure burden***

	Seizure burden (mins/h)[a]	
Period, Descriptor	**Active Comparator (StOC) N=9**	**Lacosamide N=15**
Evaluation, 1h – 3h		
n	9	11
Mean (SD)	2.45 (14.83)	6.64 (6.55)
Median (min, max)	2.51 (-32.4, 19.6)	4.74 (-0.9, 22.0)

CSR=clinical study report; FAS=full analysis set; h=hour; mins=minutes; StOC=standard of care
Note: Participants who received rescue medication at any time between the first dose and 3 hours after the first dose were excluded from the analysis.
a The absolute reduction in seizure burden from baseline was assessed by treatment group.

Secondary efficacy variables: During the evaluation period (1 to 3 hours), the responder proportions in the LCM and active comparator groups were similar, 60.0% and 66.7%, respectively, and 60% of participants in the lacosamide group and 44.4% of participants in the active comparator group had at least 80% reduction in seizure burden regardless of seizure severity. The median time to response across 48 hours was 3.0 hours for both groups, and the median time to seizure freedom was 3.0 hours in the lacosamide and 8.0 hours in the active comparator groups. The mean (SD) percent reduction in seizure burden at 3 hours was 84.41 (36.42) in the lacosamide group and 30.26 (114.17) in the active comparator group.

Safety results

The safety results observed in neonates were consistent with the known safety profile of lacosamide in older children and adults with epilepsy. No new safety concerns were identified.

The incidence of all TEAEs reported during the study is presented for the safety set in Table 6.

Table 6. ***Summary of AEs (safety set)***

Category	**Active Comparator (StOC) N=12 n (%) [#]**	**Lacosamide N=14 n(%) [#]**	**All participants N=26 n (%) [#]**
Any TEAEs	5 (41.7) [21]	9 (64.3) [21]	14 (53.8) [42]
Serious TEAEs	0	2 (14.3) [2]	2 (7.7) [2]
Nonserious TEAEs	5 (41.7) [21]	8 (57.1) [19]	13 (50.0) [40]

Participant discontinuations due to TEAEs	0	0	0
Permanent discontinuations of study treatment due to TEAEs	0	0	0
Drug-related TEAEs	0	1 (7.1) [2]	1 (3.8) [2]
Severe TEAEs	1 (8.3) [1]	3 (21.4) [3]	4 (15.4) [4]
All deaths (AEs leading to deaths)	0	1	1
Deaths (TEAEs leading to deaths)	0	1 (7.1) [1]	1 (3.8) [1]

AE=adverse event; StOC=standard of care; TEAE=treatment-emergent adverse event
Note: n=number of participants reporting at least 1 TEAE in that category.
Note: [#] is the number of individual occurrences of the TEAE in that category.
Note: All Deaths was based on all participants screened and refers to all deaths occurring on the study.
Note: TEAEs were defined as AEs which had onset on or after the start date and time of the first dose of study treatment.

The most common TEAEs in the lacosamide group were convulsion and vomiting (each reported by 2 participants. In the active comparator group, none of the TEAEs were reported by >1 participant. Overall, 9 study participants (34.6%) experienced TEAEs with a maximum intensity of mild and 4 participants (15.4%) experienced severe TEAEs. In the lacosamide group, 3 participants (21.4%) experienced a single severe TEAE each (congenital CNS anomaly, cerebral infarction, and pulmonary oedema); none of these were considered related to lacosamide by the Investigator. In the active comparator group, 1 participant (8.3%) experienced a severe TEAE (cerebral ischaemia); the event was considered not related to the study treatment by the Investigator and resolved. In the lacosamide group, 1 study participant experienced 2 TEAEs (convulsion and lethargy) that were considered related to lacosamide by the Investigator. These TEAEs were mild and resolved. No study participant in the active comparator group experienced a drug-related TEAE. In the lacosamide group, 1 study participant experienced a fatal TEAE of congenital CNS anomaly; the event was considered not related to lacosamide by the Investigator. No study participant in the active comparator group experienced a fatal TEAE. None of the TEAEs in the study led to permanent discontinuation of study treatment.

No consistent or clinically relevant treatment-related changes from baseline in vital signs values were observed after lacosamide or active comparator treatment. There were no participants with abnormal, clinically significant ECG findings in the lacosamide group during the treatment period. One participant in the active comparator group had abnormal, clinically significant ECG findings at the safety follow-up visit.

CL0447-Part V: *Update of the CL0447-Part IV population PK model for lacosamide using data from study SP0968 in neonates*

Description and Methods

CL0447-Part V was a final retrospective population PK model in children from birth to <18 years of age. The main objectives of this report were to:

- Update the lacosamide paediatric PK model developed in CL0447-Part IV with a focus on neonates using available lacosamide PK data from study SP0968 in neonates
- Perform simulations to evaluate the exposure in neonates versus adults

SP0968 investigated the PK of lacosamide in neonates; a total of 16 study participants in the lacosamide treatment group was planned, with each participant providing up to 6 PK results during the 96-hour Treatment Period for the analysis of lacosamide serum concentrations.

CL0447-Part V is considered the final retrospective population PK model of lacosamide in children from birth to <18 years of age, combining all available data at the end of the paediatric program.

Results

A summary of lacosamide serum concentrations after infusion on Day 1 is presented for the PK-PPS in Table 7.

Table 7. ***Lacosamide serum concentrations (µg/mL) after infusion – Day 1 (PK-PPS)***

Time window	n	GeoMean	GeoCV (%)
30–90 minutes after start of 1st infusion	11	7.003	37.6
6–8 hours after start of 1st infusion	12	5.949	38.6
30–90 minutes after start of 2nd or 3rd infusion	11	13.27	29.4
6–8 hours after start of 2nd or 3rd infusion	13	9.607	39.8

CSR=clinical study report; CV=coefficient of variation; GeoMean=geometric mean; PK-PPS=Pharmacokinetic Per-Protocol Set
Note: CVs were only calculated if at least two-thirds of the concentrations were quantified at the respective time point.
Note: Samples excluded from the summary table and the reasons for exclusion are provided in SP0968 final CSR Listing 5.4.
Source: SP0968 final CSR Table 3.2

Lacosamide serum concentration (GeoMean) soon after the start of the 1st infusion (30 to 90 minutes later) was 7.003µg/mL and was generally maintained 6 to 8 hours later (5.949µg/mL) (Table 7). A similar trend was observed after the 2nd or 3rd infusion of lacosamide, but concentrations were increased due to accumulation. Lacosamide serum concentrations (GeoMean) were up to 13.27µg/mL at 30 to 90 minutes after the 2nd or 3rd infusion and 9.607µg/mL at 6 to 8 hours after start of the 2nd or 3rd infusion. Interparticipant variability was less than 40%.

2.3.3. Discussion on clinical aspects

Study SP0968 was a phase 2/3, multi-centre, open-label, randomised study evaluating the use of lacosamide versus an active comparator in neonates with seizures that were not adequately controlled with previous anti-epileptic drug treatment. It aimed to evaluate the efficacy, safety, tolerability, and PK of lacosamide in neonates ≥34 weeks of CGA, <46 weeks of CGA, and <28 days of PNA.

During the evaluation period (1 to 3 hours), study participants randomized to lacosamide and active comparator both experienced reductions in mean seizure burden, with similar percentages being considered responders. However, the interpretation of these efficacy results is limited by the small number of study participants in the full analysis set (15 participants in the lacosamide group and 9 participants in the active comparator group). Since the study was stopped prematurely due to infeasibility of enrolment, the planned Bayesian analysis could not be performed. Therefore, the primary efficacy analysis was conducted using descriptive statistics only.

No new safety concerns that require regulatory action at this stage were identified in study SP0968. The safety results observed in 26 study participants aged ≥34 weeks of CGA, <46 weeks of CGA, and <28 days of PNA with repeated ENS were consistent with the known safety profile of lacosamide in older children and adults with epilepsy.

Neonates in the lacosamide group received a dose of 15mg/kg/day, administered in 3 divided doses (5mg/kg three times a day without titration) via 30-minute iv infusions. The observed serum concentrations measured after the 1st, 2nd, and 3rd infusion indicate that the exposure is comparable that previously accepted for iv dosing in the paediatric population. The population PK analysis has not been assessed within this procedure, and a full assessment will be performed in a future Type II variation.

The MAH currently requests no changes to the Vimpat product information based on the data submitted within this Article 46 procedure. Instead, the MAH is planning the submission of a separate variation in the first half of 2026, upon the completion of the ongoing epidemiological study on long-term neurodevelopmental outcomes (EP0223). This Type II variation will encompass a comprehensive package of all available data on lacosamide in neonates, in support of proposed SmPC updates for Vimpat.

No further assessment of efficacy data from Study SP0968 is therefore conducted within this P46 procedure. A new submission within the context of a type 2 variation procedure, along with any available supportive data, is appropriate. The assessment will be challenging due to the small sample size in study SP0968. The description of study results in the forthcoming type 2 variation should therefore be as detailed as possible and contextualised in relation to the totality of supportive data available.

The benefit-risk balance remains favourable in the approved indications.

3. CHMP overall conclusion and recommendation

The results of the study SP0968 and the CL0447-Part V population PK model are being submitted in accordance with Article 46 of Regulation (EC) No 1901/2006 (The Paediatric Regulation). The MAH proposed no changes to the approved EU Summary of Product Information for Vimpat with this submission based on the study results. Instead, a separate Type II variation in support of the intended SmPC updates is planned to be submitted in the first half of 2026. The MAH proposal is supported by the Rapporteur. The benefit risk balance remains unchanged.

☒ **Fulfilled:**

No further action required, however further data are expected in the context of a variation prior any conclusion on product information amendments is made.