

Supplemental Information

Supplemental Methods

Additional eligibility criteria

To be eligible, patients were required to have had an electroencephalogram (EEG) report consistent with idiopathic generalised epilepsy. If patients had a vagus nerve stimulator implanted, it must have been in place for ≥ 6 months with a constant stimulator setting for ≥ 28 days before Visit 1 and during the Prospective Baseline and Treatment period. Patients were excluded if they had a history of focal-onset seizures or EEG findings indicative of focal-onset seizures, had symptomatic generalised epilepsy (epileptic encephalopathies) (eg, Lennox-Gastaut syndrome typically presenting with seizures including tonic seizures), some other related syndromes like Doose syndrome (typically presenting with myoclonic-atonic seizures), or evidence of both focal and generalised epilepsy, a history of convulsive status epilepticus 1 year before screening, or a current or previous diagnosis of pseudoseizures (psychogenic non-epileptic seizures), conversion disorders or other non-epileptic ictal events which could have been confused with seizures. In addition, patients were excluded if they had any medical or psychiatric condition which, in the opinion of the investigator, could have jeopardised their health or compromised their ability to participate in the trial, or had a history of suicide attempt or suicidal ideation in the past 6 months. Patients had to be withdrawn from the trial if they were unable to attain at least the minimum maintenance target dose, required a subsequent dose increase after dose reduction during the Maintenance period or required more than one dose reduction during the Maintenance period. Patients were withdrawn if they developed a second- or third-degree atrioventricular block, became pregnant, had a positive response for suicidal ideation on the Columbia-Suicide Severity Rating Scale (patients ≥ 6 years of age) or had liver function test results of transaminases ≥ 3 times the upper limit of normal (ULN) and total bilirubin ≥ 2 times ULN or transaminases ≥ 5 times ULN. Patients were further withdrawn if the sponsor or a regulatory agency requested withdrawal of the patient or if the patient was unwilling or unable to continue and withdrew consent.

Randomisation details

Treatment was assigned via an Interactive Response Technology (IRT) using a pre-determined randomisation schedule that was produced by the IRT vendor. All sponsor, investigator sites and other staff involved with the trial were blinded to the treatment code. The randomisation schedule was maintained in a secure location until the trial was unblinded. The IRT generated individual assignments for patient kits of trial medication according to the

visit schedule. Lacosamide oral solution and matching placebo were colourless to pale yellow in appearance and were packaged in identical bottles. Lacosamide and matching placebo tablets were white, oval tablets debossed with 'SP' on one side and were packaged in identical bottles.

Other outcomes

Other efficacy variables related to health outcomes were change from Baseline in Patient-Weighted Quality of Life in Epilepsy Inventory-Form 31 (QOLIE-31-P) total and subscale scores (patients ≥ 18 years) or change from Baseline in the PedsQL subscale and total scores (patients < 18 years), change from Baseline to end of treatment in the 3-Level EuroQoL-5 Dimension Quality of Life Assessment (EQ-5D-3L) visual analogue scale score and change in utility as converted from the five dimensions (patients ≥ 12 years of age), healthcare resource use (medical procedures, hospitalisation and healthcare provider visits), number of working/school days lost by patients due to epilepsy, and number of days with help from a caregiver due to epilepsy.

Other safety outcomes were discontinuations due to adverse events, incidence of new seizure types during the Treatment period, patients with increase in the days with absence/myoclonic seizures per 28 days relative to the Prospective Baseline, changes in haematology, chemistry, endocrinology and urinalysis parameters, changes in 12-lead electrocardiograms (ECGs), vital sign measurements, and physical/neurological examinations, behavioural assessment (Achenbach Child Behavior Checklist [CBCL]/1½–5 or CBCL/6–18), and cognitive function assessment (BRIEF-P or BRIEF) for paediatric patients only.

Additional details of statistical analyses

The per-protocol set (PPS) was a subset of the FAS that excluded patients who completed < 6 weeks of treatment and patients with important protocol deviations that could have affected interpretation of the primary efficacy analysis.

The primary outcome (time to second primary generalised tonic-clonic seizure [PGTCS] during 24-week Treatment period) was evaluated using a Cox proportional hazards regression model,¹ with an effect for treatment, stratifying for patients' baseline PGTCS frequency and age at informed consent (strata used: ≤ 2 PGTCS per 28 days and paediatric; ≤ 2 PGTCS per 28 days and adult; > 2 PGTCS per 28 days). The stratified hazard ratio (HR) was calculated using the placebo group as reference, and 95% confidence intervals (CIs) for the HR were also reported. An HR < 1 indicates a difference between the treatment groups favouring lacosamide over placebo. A Kaplan-Meier plot for time to event and Kaplan-Meier estimates for the median time to event and 95% CIs were provided. The number of events (for the Titration period [Day 42], first 12 weeks of the Treatment period [Day 84] and 24-week

Treatment period [Day 166]) as well as the percentage of patients who were censored (patients who completed the Treatment period without having a second PGTCS) were reported. Time to first PGTCS during the 24-week Treatment period was assessed similarly (without p-value).

Freedom from PGTCS for the 24-week Treatment period was evaluated using an extended Mantel-Haenszel testing procedure which considered that patients were initially stratified for their baseline PGTCS frequency and age at informed consent. The number and percentage of patients who experienced a PGTCS or censoring were presented for each stratum and overall. The stratified PGTCS freedom rate (and two-sided 95% CI) at Day 166 for each treatment group and the difference between treatment groups were presented. A gatekeeping strategy² was used to test the key secondary efficacy variable at the 5% significance level provided that the primary endpoint was statistically significant at the 5% level. If the primary endpoint failed to reach statistical significance, then the key secondary efficacy endpoint was exploratory only. Descriptive analyses were performed for all other efficacy and safety assessments.

Analyses of absence or myoclonic seizures were restricted to the subset of patients who reported a history of absence or myoclonic seizures or reported absence or myoclonic seizures during the Combined Baseline or the 24-week Treatment Period.

Treatment-emergent adverse events (TEAEs) were defined as adverse events that started (or whose intensity worsened) on or after the date of first dose of trial medication and within 30 days following the date of last trial medication administration. TEAEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 16.1.

Supplemental Results

Sensitivity analyses of the primary outcome

The results of all sensitivity analyses of time to second PGTCS were consistent with the primary analysis, including analyses based on the PPS (104 patients on lacosamide and 103 patients on placebo who completed at least 6 weeks of treatment and had no important protocol deviations; one patient in the lacosamide group was re-diagnosed with focal seizures during the trial and was excluded from the PPS) and full analysis set, analyses evaluating the effect of different types of discontinuations, and an analysis including all 126 events that occurred during the trial (one patient in the lacosamide group was randomised after the 125th event and not included in the primary analysis).

Additional safety, quality of life and health outcomes

There was no evidence for any clinically relevant effect of lacosamide treatment on clinical chemistry, endocrinology, haematology, or urinalysis laboratory parameters, vital signs, neurological examinations, Achenbach CBCL and BRIEF-P/BRIEF assessments. Mean and median changes from Baseline to last visit for all 12-lead ECG parameters were small, with the exception of mean change in PR interval, which was 9.96 ms with lacosamide versus -0.79 ms with placebo. No clinically relevant changes from Baseline were observed.

The incidence of TEAEs related to abnormal ECG findings was generally low and similar between lacosamide and placebo.

Changes from Baseline to last visit for QOLIE-31-P total and subscale scores, distress items, and prioritisation items, PedsQL and EQ-5D-3L quality of life visual analogue scale scores were generally small and variable with both lacosamide and placebo. No worsening was observed in any of the assessed health outcome measures.

References

1. Cox DR. Regression models and life-tables. *J R Stat Soc Series B Methodol* 1972;34:187–220.
2. Marcus R, Peritz E, Gabriel KR. On closed testing procedures with special reference to ordered analysis of variance. *Biometrika* 1976;63:655–60.

Supplemental Tables

Table S1 Epileptic syndrome and epilepsy aetiology (SS)

	Placebo (n=121)	Lacosamide (n=121)
Classification of epileptic syndrome*, n (%)		
Generalised idiopathic	121 (100)	121 (100)
Benign neonatal convulsions	0	1 (0.8)
Benign myoclonic epilepsy in infancy	0	1 (0.8)
Childhood absence epilepsy	6 (5.0)	9 (7.4)
Juvenile absence epilepsy	15 (12.4)	13 (10.7)
Juvenile myoclonic epilepsy	42 (34.7)	34 (28.1)
Epilepsy with grand mal seizures on awakening	19 (15.7)	15 (12.4)
Other generalised idiopathic epilepsies	54 (44.6)	55 (45.5)
Epilepsies with seizures precipitated by specific modes of activation	6 (5.0)	6 (5.0)
Generalised symptomatic	1 (0.8)	0
Other symptomatic generalised epilepsies	1 (0.8)	0
Situation-related seizures	4 (3.3)	1 (0.8)
Aetiology of epilepsy, n (%)		
Aetiology known	18 (14.9)	17 (14.0)
Genetic origin (familial epilepsy)	18 (14.9)	16 (13.2)
Cranial trauma	0	1 (0.8)
Aetiology unknown	103 (85.1)	104 (86.0)
Idiopathic	103 (85.1)	100 (82.6)
Cryptogenic	0	4 (3.3)

*Patients could have more than one response in a classification level and/or category. SS, safety set.

Table S2 Proportion of patients free from PGTCS at the end of the 24-week Treatment period (Day 166) (FAS)

	Placebo (n=121)	Lacosamide (n=118)*
All patients		
Number of patients with a seizure, n (%)	97 (80.2)	79 (66.9)
Number of patients censored [†] , n (%)	24 (19.8)	39 (33.1)
KM seizure-free (stratified) [‡] , % (95% CI)	17.2 (10.4 to 24.0)	31.3 (22.8 to 39.9)
Difference between lacosamide and placebo KM seizure-free (stratified) [‡] (95% CI)	14.1 (3.2 to 25.1); p=0.011 [§]	
≤2 PGTCS per 28 days at baseline and paediatric	n=21	n=21
Number of patients with a seizure, n (%)	18 (85.7)	16 (76.2)
Number of patients censored [†] , n (%)	3 (14.3)	5 (23.8)
KM seizure-free, % (95% CI)	14.3 (0.0 to 29.3)	22.9 (4.4 to 41.3)
≤2 PGTCS per 28 days at baseline and adult	n=74	n=72
Number of patients with a seizure, n (%)	56 (75.7)	46 (63.9)
Number of patients censored [†] , n (%)	18 (24.3)	26 (36.1)
KM seizure-free, % (95% CI)	22.3 (12.5 to 32.1)	34.2 (23.0 to 45.5)
>2 PGTCS per 28 days at baseline	n=26	n=25
Number of patients with a seizure, n (%)	23 (88.5)	17 (68.0)
Number of patients censored [†] , n (%)	3 (11.5)	8 (32.0)
KM seizure-free, % (95% CI)	4.9 (0.0 to 14.3)	30.0 (11.3 to 48.7)

*One patient in the lacosamide group was randomised after the 125th event and does not appear in this analysis. [†]Patients censored before Day 166 (patients who did not have a seizure or did not stay in the trial for 166 days). [‡]Estimated by Mantel-Haenszel methods (taking into account the stratification for the following combinations of patients' baseline PGTCS frequency and age group: ≤2 PGTCS per 28 days in the Combined Baseline period and paediatric; ≤2 PGTCS per 28 days in the Combined Baseline period and adult; >2 PGTCS per 28 days in the Combined Baseline period); [§]Based on a chi-square test on one degree of freedom. CI, confidence interval; FAS, full analysis set; KM, Kaplan-Meier; PGTCS, primary generalised tonic-clonic seizure.

Table S3 Percent change from Combined Baseline in PGTCS frequency per 28 days (FAS)

	Placebo (n=121)	Lacosamide (n=119)
PGTCS frequency per 28 days during Combined Baseline, median (range)	1.24 (0.7 to 19.4)	1.25 (0.3 to 12.3)
Percent change from Combined Baseline in PGTCS frequency per 28 days, median (range)		
6-week Titration	-42.71 (-100.0 to 715.4)	-66.37 (-100.0 to 943.6)
12-week Treatment*	-55.69 (-100.0 to 715.4)	-71.33 (-100.0 to 943.6)
24-week Treatment†	-43.24 (-100.0 to 715.4)	-77.92 (-100.0 to 943.6)

*6-week Titration period + first 6 weeks of Maintenance period; †6-week Titration period + 18-week Maintenance period.
FAS, full analysis set; PGTCS, primary generalised tonic-clonic seizure.

Table S4 Percent change from Prospective Baseline in days with absence seizures and days with myoclonic seizures per 28 days (SS)

Absence seizures	Placebo (n=42)	Lacosamide (n=51)
Days with absence seizures per 28 days during Prospective Baseline, median (range)*	1.5 (0–28)	0.0 (0–28)
Percent change from Prospective Baseline in days with absence seizures, median (range)†	n=22	n=22
6-week Titration	-11.1 (-100 to 183)	-24.6 (-100 to 155)
12-week Treatment‡	-13.3 (-100 to 183)	-30.4 (-100 to 155)
24-week Treatment§	-15.3 (-100 to 183)	-30.1 (-100 to 155)
Myoclonic seizures	Placebo (n=49)	Lacosamide (n=47)
Days with myoclonic seizures per 28 days during Prospective Baseline, median (range)*	1.0 (0 to 28)	2.0 (0 to 28)
Percent change from Prospective Baseline in days with myoclonic seizures, median (range)†	n=25	n=24
6-week Titration	-51.8 (-100 to 57)	-32.5 (-100 to 402)
12-week Treatment‡	-65.7 (-100 to 87)	-43.8 (-100 to 402)
24-week Treatment§	-65.7 (-100 to 87)	-54.6 (-100 to 402)

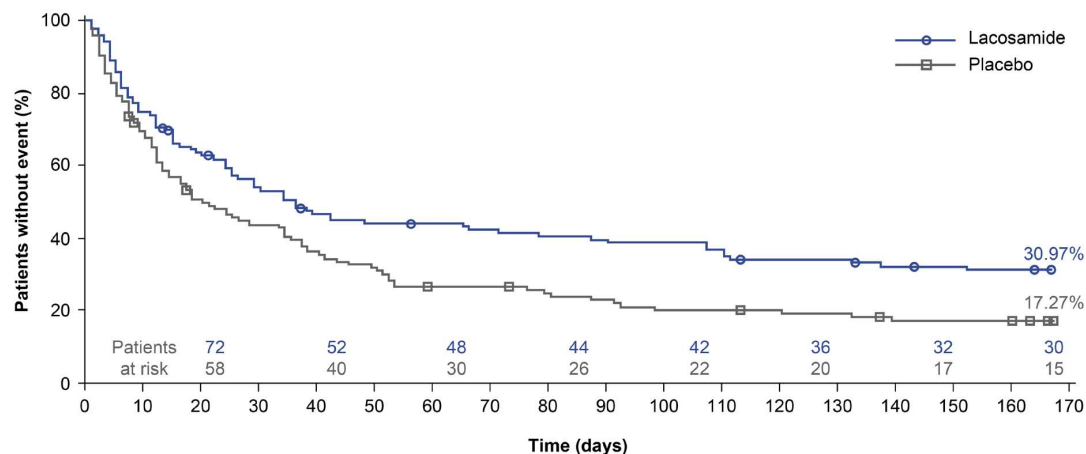
*Based on average seizure days over 28 days for patients who reported a history of absence/myoclonic seizures or an occurrence of absence/myoclonic seizures in the Combined Baseline or Treatment period; †Based on patients with absence/myoclonic seizure days during the Prospective Baseline; ‡6-week Titration period + first 6 weeks of Maintenance period; §6-week Titration period + 18-week Maintenance period. SS, safety set.

Table S5 TEAEs by number of concomitant AEDs* (SS)

	One concomitant AED		Two concomitant AEDs		Three concomitant AEDs	
	Placebo (n=44)	Lacosamide (n=35)	Placebo (n=55)	Lacosamide (n=62)	Placebo (n=21)	Lacosamide (n=23)
Any TEAEs, n (%)	27 (61.4)	28 (80.0)	34 (61.8)	48 (77.4)	17 (81.0)	19 (82.6)
TEAEs[†] experienced during the Treatment period by ≥5% of all patients on placebo or lacosamide, n (%)						
Dizziness	2 (4.5)	7 (20.0)	4 (7.3)	15 (24.2)	1 (4.8)	6 (26.1)
Somnolence	2 (4.5)	6 (17.1)	10 (18.2)	10 (16.1)	5 (23.8)	4 (17.4)
Headache	5 (11.4)	5 (14.3)	5 (9.1)	5 (8.1)	2 (9.5)	7 (30.4)
Nausea	0	3 (8.6)	5 (9.1)	7 (11.3)	2 (9.5)	2 (8.7)
Vertigo	0	1 (2.9)	2 (3.6)	4 (6.5)	0	3 (13.0)
Nasopharyngitis	2 (4.5)	2 (5.7)	1 (1.8)	4 (6.5)	1 (4.8)	2 (8.7)
Fatigue	3 (6.8)	4 (11.4)	1 (1.8)	3 (4.8)	2 (9.5)	1 (4.3)
Vomiting	0	0	1 (1.8)	5 (8.1)	0	2 (8.7)

*One patient on lacosamide had no concomitant AEDs at trial entry and one patient on placebo had five concomitant AEDs at trial entry; both were excluded from this analysis; [†]MedDRA (Version 16.1) preferred term. AED, antiepileptic drug; MedDRA, Medical Dictionary for Regulatory Activities; SS, safety set; TEAE, treatment-emergent adverse event.

Supplemental Figure

Figure S1 Kaplan-Meier estimates for time to first PGTCs (125 events) (FAS)

One patient in the lacosamide group was randomised after the 125th event and does not appear in this analysis. Symbols represent censored patients (patients who completed the Treatment period without having a first PGTCs). The cumulative number of events during the 24-week Treatment period (by Day 166) was 79 with lacosamide (Titration period [by Day 42]: 64; first 12 weeks of Treatment period [by Day 84]: 69) and 97 with placebo (Titration period [by Day 42]: 78; first 12 weeks of Treatment period [by Day 84]: 90). FAS, full analysis set; PGTCs, primary generalised tonic-clonic seizure.

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