Clinical trial results:
An Open-label, Multicenter, Extension Study to Evaluate the Long-term Safety, Tolerability, and Efficacy of UCB0942 When Used as Adjunctive Therapy for Partial-onset Seizures in Adult Subjects With Highly Drug-resistant Focal Epilepsy

Summary

EudraCT number	2015-001268-20
Trial protocol	NL DE BE BG HU ES IT
Global end of trial date	24 November 2020

Results information

Result version number	v1 (current)
This version publication date	13 December 2021
First version publication date	13 December 2021

Trial information

Trial identification

Sponsor protocol code	EP0073

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02625090
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, 1070
Public contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com
Scientific contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	21 December 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 November 2020
Global end of trial reached?	Yes
Global end of trial date	24 November 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term safety and tolerability of UCB0942 at individualized doses between 100 milligrams (mg)/day to a maximum of 800 mg/day in participants with highly drug-resistant focal epilepsy

Protection of trial subjects:

During the conduct of the study all participants were closely monitored, including review of echocardiograms to detect cardiac adverse events.

Background therapy:

Background therapy as permitted in the protocol.

Evidence for comparator:

Not applicable

Actual start date of recruitment	03 December 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 6
Country: Number of subjects enrolled	Bulgaria: 2
Country: Number of subjects enrolled	Germany: 7
Country: Number of subjects enrolled	Hungary: 3
Country: Number of subjects enrolled	Netherlands: 3
Country: Number of subjects enrolled	Spain: 21
Worldwide total number of subjects	42
EEA total number of subjects	42

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	42
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll study participants in December 2015 and concluded in November 2020.

Pre-assignment

Screening details:

Participant flow refers to the Safety Set. Participants who experienced substantial benefit from UCB0942 with acceptable tolerability in the EP0069 (NCT02495844) study had opportunity to continue treatment in this study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	UCB0942

Arm description:

All enrolled participants continued the same UCB0942 dose which they were receiving during last visit of study EP0069 and the dose could be further increased or decreased in participants to optimize the drug tolerability and seizure control for each participant. Daily UCB0942 film-coated tablets were administered orally in doses of 100 milligrams (mg) (50 mg twice daily [bid]), 200 mg (100 mg bid), 400 mg (200 mg bid), 600 mg (300 mg bid), or 800 mg (400 mg bid) for up to approximately 5 years.

Arm type	Experimental
Investigational medicinal product name	UCB0942
Investigational medicinal product code	UCB0942
Other name	Padsevonil
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

All enrolled participants received UCB0942 film-coated tablets daily administered orally during the study allowed in doses 100 mg (50 mgbid), bid), 200 mg (100mg bid), 400 mg (200 mg bid), 600 mg (300 mg bid), or 800 mg (400 mg bid) for up to approximately 5 years.

Number of subjects in period 1	UCB0942
Started	42
Completed	0
Not completed	42
Sponsor's Decision	9
Study terminated by Sponsor	7
Protocol Deviation	2
Adverse event, non-fatal	3
Somnolence	1
Participant wants to be pregnant	2
For the Promoter	1

Negative Benefit/Risk	1
Lack of efficacy	16

Baseline characteristics

Reporting groups	
Reporting group title	UCB0942

Reporting group description:

All enrolled participants continued the same UCB0942 dose which they were receiving during last visit of study EP0069 and the dose could be further increased or decreased in participants to optimize the drug tolerability and seizure control for each participant. Daily UCB0942 film-coated tablets were administered orally in doses of 100 milligrams (mg) (50 mg twice daily [bid]), 200 mg (100 mg bid), 400 mg (200 mg bid), 600 mg (300 mg bid), or 800 mg (400 mg bid) for up to approximately 5 years.

Reporting group values	UCB0942	Total	
Number of subjects	42	42	
Age Categorical Units: participants			
<=18 years	0	0	
Between 18 and 65 years	42	42	
>=65 years	0	0	
Age Continuous Units: years			
arithmetic mean	35.4		
standard deviation	± 10.5	-	
Sex: Female, Male Units: participants			
Female	21	21	
Male	21	21	

End points

End points reporting groups

Reporting group title	UCB0942

Reporting group description:

All enrolled participants continued the same UCB0942 dose which they were receiving during last visit of study EP0069 and the dose could be further increased or decreased in participants to optimize the drug tolerability and seizure control for each participant. Daily UCB0942 film-coated tablets were administered orally in doses of 100 milligrams (mg) (50 mg twice daily [bid]), 200 mg (100 mg bid), 400 mg (200 mg bid), 600 mg (300 mg bid), or 800 mg (400 mg bid) for up to approximately 5 years.

Subject analysis set title	UCB0942 (SS)
Subject analysis set type	Safety analysis

Subject analysis set description:

All enrolled participants continued the same UCB0942 dose which they were receiving during last visit of study EP0069 and the dose could be further increased or decreased in participants to optimize the drug tolerability and seizure control for each participant. Daily UCB0942 film-coated tablets were administered orally in doses of 100 mg (50 mg bid), 200 mg (100 mg bid), 400 mg (200 mg bid), 600 mg (300 mg bid), or 800 mg (400 mg bid) for up to approximately 5 years. Participants formed the Safety Set (SS).

Subject analysis set title	UCB0942 (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

All enrolled participants continued the same UCB0942 dose which they were receiving during last visit of study EP0069 and the dose could be further increased or decreased in participants to optimize the drug tolerability and seizure control for each participant. Daily UCB0942 film-coated tablets were administered orally in doses of 100 mg (50 mg bid), 200 mg (100 mg bid), 400 mg (200 mg bid), 600 mg (300 mg bid), or 800 mg (400 mg bid) for up to approximately 5 years. Participants formed the FAS.

Primary: Percentage of participants experiencing at least one Treatment-Emergent Adverse Event (TEAE) from the beginning at Entry Visit (EV) of the Evaluation Period to End of Safety Follow-Up Visit during the EP0073 study

End point title	Percentage of participants experiencing at least one Treatment-Emergent Adverse Event (TEAE) from the beginning at Entry Visit (EV) of the Evaluation Period to End of Safety Follow-Up Visit during the EP0073 study[1]

End point description:

An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. Percentage of participants experiencing at least one treatment-emergent adverse event (reported by the participant and/or caregiver or observed by the Investigator or inpatient staff) are reported. The Safety Set (SS) consisted of all enrolled study participants who took at least 1 dose of UCB0942 in the EP0073 study.

End point type	Primary

End point timeframe:

From Entry Visit to End of Safety Follow-Up Visit (up to 5 years)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (SS)			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: percentage of participants				
number (not applicable)	90.5			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >3-6) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >3-6) over the Evaluation Period[2]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >3-6)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: percentage of participants				
number (not applicable)	24.4			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month 0 to 3) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month 0 to 3) over the Evaluation Period[3]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The full analysis set (FAS) consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure

diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month 0-3)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: percentage of participants				
number (not applicable)	24.4			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >6-9) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >6-9) over the Evaluation Period[4]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >6-9)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: percentage of participants				
number (not applicable)	20.6			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >9-12) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >9-12) over the Evaluation Period[5]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >9-12)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: percentage of participants				
number (not applicable)	28.6			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >12-15) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >12-15) over the Evaluation Period[6]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >12-15)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	26			
Units: percentage of participants				
number (not applicable)	23.1			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >15-18) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >15-18) over the Evaluation Period[7]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >15-18)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	26			
Units: percentage of participants				
number (not applicable)	23.1			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >18-21) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >18-21) over the Evaluation Period[8]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during

the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >18-21)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	26			
Units: percentage of participants				
number (not applicable)	26.9			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >21-24) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >21-24) over the Evaluation Period[9]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >21-24)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: percentage of participants				
number (not applicable)	27.3			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >24-27) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >24-27) over the Evaluation Period[10]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >24-27)

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	23			
Units: percentage of participants				
number (not applicable)	26.1			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >27-30) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >27-30) over the Evaluation Period[11]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >27-30)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	21			
Units: percentage of participants				
number (not applicable)	33.3			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >30-33) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >30-33) over the Evaluation Period[12]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >30-33)

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: percentage of participants				
number (not applicable)	25.0			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >33-36) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >33-36) over the Evaluation Period[13]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during

the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >33-36)

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: percentage of participants				
number (not applicable)	35.0			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >36-39) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >36-39) over the Evaluation Period[14]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >36-39)

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: percentage of participants				
number (not applicable)	27.8			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >42-45) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >42-45) over the Evaluation Period[15]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >42-45)

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	14			
Units: percentage of participants				
number (not applicable)	50.0			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >39-42) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >39-42) over the Evaluation Period[16]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >39-42)

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: percentage of participants				
number (not applicable)	27.8			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >45-48) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >45-48) over the Evaluation Period[17]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >45-48)

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: percentage of participants				
number (not applicable)	40.0			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >51-54) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >51-54) over the Evaluation Period[18]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during

the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >51-54)

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: percentage of participants				
number (not applicable)	40.0			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >48-51) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >48-51) over the Evaluation Period[19]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >48-51)

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: percentage of participants				
number (not applicable)	40.0			

Statistical analyses

No statistical analyses for this end point

Primary: 75% Responder Rate by 3-month interval (Month >54-57) over the Evaluation Period

End point title	75% Responder Rate by 3-month interval (Month >54-57) over the Evaluation Period[20]

End point description:

A 75% responder is defined as a participant with a ≥75% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 75% responders during the Period/ number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment.

End point type	Primary

End point timeframe:

Over 3-month interval over the Evaluation Period (Month >54-57)

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was done, as this is an open label study with only one treatment arm. Thus no statistical comparison is possible.

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	1			
Units: percentage of participants				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Median partial-onset seizure frequency per 28 days by 3-month intervals over the Evaluation Period of the EP0073 study

End point title	Median partial-onset seizure frequency per 28 days by 3-month intervals over the Evaluation Period of the EP0073 study

End point description:

Median partial-onset seizure frequency per 28 days by 3-month intervals over the Evaluation Period of the EP0073 study was reported. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, 'n' signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Over the 3-month interval: Month 0-3, >3-6, >6-9, >9-12, >12-15, >15-18, >18-21, >21-24, >24-27, >27-30, >30-33, >33-36, >36-39, >39-42, >42-45, >45-48, >48-51, >51-54, >54-57 over the Evaluation Period

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: seizure frequency per 28 days				
median (inter-quartile range (Q1-Q3))				
Month 0-3 (n=42)	18.98 (10.89 to 48.22)			
Month >3-6 (n=42)	22.99 (13.07 to 66.18)			
Month >6-9 (n=35)	23.33 (8.09 to 56.00)			
Month >9-12 (n=29)	18.67 (6.84 to 37.96)			
Month >12-15 (n=27)	23.23 (9.02 to 49.47)			
Month >15-18 (n=27)	19.91 (11.20 to 41.48)			
Month >18-21 (n=27)	16.80 (8.09 to 42.00)			
Month >21-24 (n=23)	14.31 (5.91 to 36.09)			
Month >24-27 (n=24)	14.31 (8.71 to 38.53)			
Month >27-30 (n=22)	14.16 (5.91 to 38.58)			
Month >30-33 (n=21)	16.80 (7.78 to 42.62)			
Month >33-36 (n=21)	19.29 (6.84 to 46.67)			
Month >36-39 (n=19)	13.69 (7.16 to 45.11)			
Month >39-42 (n=19)	9.96 (5.91 to 57.24)			
Month >42-45 (n=15)	13.07 (3.73 to 63.17)			
Month >45-48 (n=11)	10.58 (2.80 to 59.42)			
Month >48-51 (n=11)	9.02 (1.56 to 48.16)			
Month >51-54 (n=6)	7.80 (3.73 to 33.60)			
Month >54-57 (n=1)	7.84 (7.84 to 7.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Median partial-onset seizure frequency per 28 days by seizure type by 3-month intervals type over the Evaluation Period of the EP0073 study

End point title	Median partial-onset seizure frequency per 28 days by seizure type by 3-month intervals type over the Evaluation Period of the EP0073 study

End point description:

Median partial-onset seizure frequency per 28 days by seizure type (Type IA1, Type IB, Type IC) by 3-month intervals over the Evaluation Period of the EP0073 study was reported. The FAS consisted of all

enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, 'n' signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Over the 3-month interval: Month 0-3, >3-6, >6-9, >9-12, >12-15, >15-18, >18-21, >21-24, >24-27, >27-30, >30-33, >33-36, >36-39, >39-42, >42-45, >45-48, >48-51, >51-54, >54-57 over the Evaluation Period

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: seizure frequency per 28 days				
median (inter-quartile range (Q1-Q3))				
Type IA1: Month 0-3 (n=42)	0.00 (0.00 to 2.18)			
Type IA1: Month >3-6 (n=42)	0.00 (0.00 to 7.47)			
Type IA1: Month >6-9 (n=35)	0.00 (0.00 to 4.36)			
Type IA1: Month >9-12 (n=29)	0.00 (0.00 to 0.00)			
Type IA1: Month >12-15 (n=27)	0.00 (0.00 to 1.24)			
Type IA1: Month >15-18 (n=27)	0.00 (0.00 to 1.87)			
Type IA1: Month >18-21 (n=27)	0.00 (0.00 to 4.36)			
Type IA1: Month >21-24 (n=23)	0.00 (0.00 to 2.80)			
Type IA1: Month >24-27 (n=24)	0.00 (0.00 to 3.27)			
Type IA1: Month >27-30 (n=22)	0.00 (0.00 to 0.93)			
Type IA1: Month >30-33 (n=21)	0.00 (0.00 to 2.49)			
Type IA1: Month >33-36 (n=21)	0.00 (0.00 to 2.49)			
Type IA1: Month >36-39 (n=19)	0.00 (0.00 to 3.42)			
Type IA1: Month >39-42 (n=19)	0.00 (0.00 to 2.80)			
Type IA1: Month >42-45 (n=15)	0.00 (0.00 to 7.47)			
Type IA1: Month >45-48 (n=11)	0.00 (0.00 to 4.67)			
Type IA1: Month >48-51 (n=11)	0.00 (0.00 to 3.73)			
Type IA1: Month >51-54 (n=6)	0.00 (0.00 to 1.87)			
Type IA1: Month >54-57 (n=1)	4.48 (4.48 to 4.48)			
Type IB: Month 0-3 (n=42)	10.73 (4.67 to 35.00)			
Type IB: Month >3-6 (n=42)	12.67 (1.56 to 28.00)			

Type IB: Month >6-9 (n=35)	9.33 (0.00 to 34.68)			
Type IB: Month >9-12 (n=29)	9.64 (1.24 to 26.11)			
Type IB: Month >12-15 (n=27)	15.56 (0.93 to 34.84)			
Type IB: Month >15-18 (n=27)	13.38 (2.18 to 37.64)			
Type IB: Month >18-21 (n=27)	13.07 (0.62 to 33.91)			
Type IB: Month >21-24 (n=23)	7.78 (0.93 to 25.20)			
Type IB: Month >24-27 (n=24)	9.80 (2.49 to 27.38)			
Type IB: Month >27-30 (n=22)	9.49 (1.87 to 33.75)			
Type IB: Month >30-33 (n=21)	9.64 (3.11 to 32.98)			
Type IB: Month >33-36 (n=21)	7.47 (2.49 to 25.67)			
Type IB: Month >36-39 (n=19)	6.53 (3.73 to 35.47)			
Type IB: Month >39-42 (n=19)	6.84 (0.31 to 24.58)			
Type IB: Month >42-45 (n=15)	5.29 (2.18 to 20.84)			
Type IB: Month >45-48 (n=11)	4.36 (1.24 to 26.96)			
Type IB: Month >48-51 (n=11)	4.67 (0.31 to 43.87)			
Type IB: Month >51-54 (n=6)	3.29 (1.06 to 33.60)			
Type IB: Month >54-57 (n=1)	3.36 (3.36 to 3.36)			
Type IC: Month 0-3 (n=42)	0.00 (0.00 to 0.00)			
Type IC: Month >3-6 (n=42)	0.00 (0.00 to 0.00)			
Type IC: Month >6-9 (n=35)	0.00 (0.00 to 0.00)			
Type IC: Month >9-12 (n=29)	0.00 (0.00 to 0.00)			
Type IC: Month >12-15 (n=27)	0.00 (0.00 to 0.00)			
Type IC: Month >15-18 (n=27)	0.00 (0.00 to 0.00)			
Type IC: Month >18-21 (n=27)	0.00 (0.00 to 0.00)			
Type IC: Month >21-24 (n=23)	0.00 (0.00 to 0.00)			
Type IC: Month >24-27 (n=24)	0.00 (0.00 to 0.00)			
Type IC: Month >27-30 (n=22)	0.00 (0.00 to 0.00)			
Type IC: Month >30-33 (n=21)	0.00 (0.00 to 0.00)			
Type IC: Month >33-36 (n=21)	0.00 (0.00 to 0.00)			
Type IC: Month >36-39 (n=19)	0.00 (0.00 to 0.31)			
Type IC: Month >39-42 (n=19)	0.00 (0.00 to 0.00)			

Type IC: Month >42-45 (n=15)	0.00 (0.00 to 0.00)			
Type IC: Month >45-48 (n=11)	0.00 (0.00 to 0.31)			
Type IC: Month >48-51 (n=11)	0.00 (0.00 to 0.31)			
Type IC: Month >51-54 (n=6)	0.00 (0.00 to 1.87)			
Type IC: Month >54-57 (n=1)	0.00 (0.00 to 0.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent change in partial-onset seizure frequency relative to the Baseline Period defined in EP0069 by 3-month intervals over the Evaluation Period of the EP0073 study

End point title	Percent change in partial-onset seizure frequency relative to the Baseline Period defined in EP0069 by 3-month intervals over the Evaluation Period of the EP0073 study

End point description:

Percent change from Baseline in seizure frequency for observable focal-onset seizures (Type IA1, IB, and IC) to the corresponding interval was calculated using the following formula: change from Baseline in the 28 day adjusted seizure frequency/28 day adjusted seizure frequency during the EP0069 2- week Prospective Outpatient Baseline Period × 100. The numerator is calculated by subtracting the 28-day adjusted seizure frequency during the Period of interest from the 28-day adjusted seizure frequency during the EP0069 2-week prospective outpatient Baseline Period. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment and 'n' signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Month 0-3, >3-6, >6-9, >9-12, >12-15, >15-18, >18-21, >21-24, >24-27, >27-30, >30-33, >33-36, >36-39, >39-42, >42-45, >45-48, >48-51, >51-54, >54-57 over the Evaluation Period, Relative to Baseline (of EP0069)

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: percent change				
median (inter-quartile range (Q1-Q3))				
Month 0-3 (n=41)	50.51 (21.74 to 72.53)			
Month >3-6 (n=41)	39.14 (12.50 to 72.78)			
Month >6-9 (n=34)	56.98 (31.19 to 72.22)			
Month >9-12 (n=28)	62.22 (39.99 to 80.54)			
Month >12-15 (n=26)	55.74 (40.95 to 72.78)			

Month >15-18 (n=26)	54.04 (35.71 to 72.72)			
Month >18-21 (n=26)	57.27 (39.42 to 76.28)			
Month >21-24 (n=22)	68.57 (46.67 to 76.67)			
Month >24-27 (n=23)	60.15 (40.31 to 77.41)			
Month >27-30 (n=21)	59.82 (44.79 to 80.06)			
Month >30-33 (n=20)	59.57 (41.94 to 76.17)			
Month >33-36 (n=20)	59.73 (35.42 to 78.96)			
Month >36-39 (n=18)	64.50 (45.56 to 78.90)			
Month >39-42 (n=18)	59.01 (37.78 to 80.06)			
Month >42-45 (n=14)	68.79 (38.39 to 80.00)			
Month >45-48 (n=10)	68.17 (56.98 to 85.00)			
Month >48-51 (n=10)	67.12 (51.67 to 91.67)			
Month >51-54 (n=5)	73.08 (61.92 to 80.00)			
Month >54-57 (n=1)	73.56 (73.56 to 73.56)			

Statistical analyses

No statistical analyses for this end point

Secondary: 50% responder rate by 3-month intervals over the Evaluation Period of the EP0073 study

End point title	50% responder rate by 3-month intervals over the Evaluation Period of the EP0073 study

End point description:

A 50% responder was defined as a participant with a ≥50% reduction in partial-onset seizure (POS) frequency for observable focal-onset seizures (Type IA1, IB, and IC) relative to the 2-week Prospective Outpatient Baseline Period defined in EP0069. It was calculated using formula: Count of 50% responders during the Period/number of participants during the Period × 100. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, number of participants analyzed included those participants who were evaluable for the assessment and 'n' signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Over the 3-month interval: Month 0-3, >3-6, >6-9, >9-12, >12-15, >15-18, >18-21, >21-24, >24-27, >27-30, >30-33, >33-36, >36-39, >39-42, >42-45, >45-48, >48-51, >51-54, >54-57 over the Evaluation Period

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: percentage of participants				
number (not applicable)				
Month 0-3 (n=41)	51.2			
Month >3-6 (n=41)	39.0			
Month >6-9 (n=34)	58.8			
Month >9-12 (n=28)	67.9			
Month >12-15 (n=26)	65.4			
Month >15-18 (n=26)	53.8			
Month >18-21 (n=26)	57.7			
Month >21-24 (n=22)	72.7			
Month >24-27 (n=23)	69.6			
Month >27-30 (n=21)	66.7			
Month >30-33 (n=20)	70.0			
Month >33-36 (n=20)	65.0			
Month >36-39 (n=18)	72.2			
Month >39-42 (n=18)	72.2			
Month >42-45 (n=14)	64.3			
Month >45-48 (n=10)	80.0			
Month >48-51 (n=10)	90.0			
Month >51-54 (n=5)	80.0			
Month >54-57 (n=1)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of seizure-free days by 3-month intervals over the Evaluation Period

End point title	Percentage of seizure-free days by 3-month intervals over the Evaluation Period

End point description:

The number of seizure-free days is defined as the total number of days within an analysis Period or time interval for which no seizures were reported. The percentage of seizure-free days is to be computed as 100 times the number of seizure-free days divided by the number of days for which daily diary data was available in the specified analysis Period. Days without the corresponding daily diary data (ie, "Not Done" is ticked) are not used in these computations. The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073. Here, 'n' signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Over the 3-month interval: Month 0-3, >3-6, >6-9, >9-12, >12-15, >15-18, >18-21, >21-24, >24-27, >27-30, >30-33, >33-36, >36-39, >39-42, >42-45, >45-48, >48-51, >51-54, >54-57 over the Evaluation Period

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: percentage of days				
median (inter-quartile range (Q1-Q3))				
Month 0-3 (n=42)	48.33 (24.44 to 76.67)			
Month >3-6 (n=42)	42.81 (8.89 to 68.89)			
Month >6-9 (n=35)	54.44 (10.00 to 80.00)			
Month >9-12 (n=29)	55.56 (25.56 to 78.89)			
Month >12-15 (n=27)	54.44 (22.22 to 78.89)			
Month >15-18 (n=27)	51.11 (25.56 to 73.33)			
Month >18-21 (n=27)	61.11 (26.67 to 80.00)			
Month >21-24 (n=23)	57.78 (30.00 to 86.67)			
Month >24-27 (n=24)	60.00 (31.11 to 77.22)			
Month >27-30 (n=22)	64.44 (22.22 to 85.56)			
Month >30-33 (n=21)	57.78 (28.89 to 80.00)			
Month >33-36 (n=21)	60.00 (21.11 to 77.78)			
Month >36-39 (n=19)	68.89 (24.44 to 77.78)			
Month >39-42 (n=19)	67.78 (16.67 to 88.89)			
Month >42-45 (n=15)	67.78 (6.67 to 86.67)			
Month >45-48 (n=11)	72.22 (11.11 to 91.11)			
Month >48-51 (n=11)	73.33 (4.00 to 94.44)			
Month >51-54 (n=6)	80.65 (6.06 to 86.67)			
Month >54-57 (n=1)	72.00 (72.00 to 72.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Seizure-free rate over the Evaluation Period

End point title	Seizure-free rate over the Evaluation Period

End point description:

Participants were considered seizure free for a given Period or time interval if the participant, completes the Period or time interval, reports no seizures during the Period, and has no more than 10% of days in the Period for which seizure data is not available (ie, "Not Done" is reported on the Seizure Count CRF). The seizure freedom rate (%) for a specific time Period will be calculated using the following formula: Count of seizure free participants during the Period/ Number of participants during the Period × 100.

The FAS consisted of all enrolled study participants who took at least 1 dose of UCB0942 and completed at least 1 seizure diary during the Evaluation Period in EP0073.

End point type	Secondary

End point timeframe:

Over the Evaluation Period (up to 5 years)

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: percentage of participants				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Changes in Quality of Life in Epilepsy 31-P (QOLIE-31-P) total score from Visit 3 (Week 2) of EP0069 through the assessment of the Evaluation Period of EP0073

End point title	Changes in Quality of Life in Epilepsy 31-P (QOLIE-31-P) total score from Visit 3 (Week 2) of EP0069 through the assessment of the Evaluation Period of EP0073

End point description:

The QOLIE-31-P includes 30 items grouped into 7 multi-item subscales (seizure worry, overall quality of life, emotional well-being, energy/fatigue, cognitive functioning, medication effects, and social function) and a health status item. Individual responses for the 30 subscale items are rescaled to 0 to 100 with higher scores reflecting better functioning. Each subscale score is then calculated by summing rescaled responses for that subscale and dividing by number of items with non-missing response. Responses for health status item are multiple of 10 ranging from 0 to 100 with higher score corresponding to better health status. The QOLIE-31-P total score was calculated as weighted sum of the subscale scores which ranges from 0 to 100 with higher score reflecting better functioning. FAS population was used. Here, number of participants analyzed included those participants who were evaluable for the assessment and 'n' signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Month 3, 7, 13, 19, 25, 31, 37, 43, 49, early discontinuation visit (EDV) (up to Month 58), Relative to Baseline (of EP0069)

End point values	UCB0942 (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	39			
Units: scores on a scale				
arithmetic mean (standard deviation)				
Month 3 (n=39)	3.1 (± 14.2)			
Month 7 (n=31)	3.8 (± 17.0)			
Month 13 (n=25)	6.8 (± 17.7)			
Month 19 (n=24)	5.7 (± 18.0)			

Month 25 (n=22)	4.7 (± 24.8)			
Month 31 (n=20)	5.4 (± 21.7)			
Month 37 (n=18)	3.4 (± 18.8)			
Month 43 (n=13)	1.0 (± 19.0)			
Month 49 (n=4)	-4.6 (± 22.2)			
EDV (up to Month 58) (n=38)	2.2 (± 19.9)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Entry Visit to End of Safety Follow-Up Visit (up to approximately 5 years)

Adverse event reporting additional description:

Treatment-emergent adverse events (TEAEs) were defined as adverse events (AEs) that started on or after the first dose of UCB0942 in EP0073 or AEs whose intensity worsened on or after the date of first dose of UCB0942 in EP0073.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	UCB0942 (SS)

Reporting group description:

All enrolled participants continued the same UCB0942 dose which they were receiving during last visit of study EP0069 and the dose could be further increased or decreased in participants to optimize the drug tolerability and seizure control for each participant. Increases or decreases to the dose of UCB0942 was made in steps not exceeding 200 mg/day per week however, 800 mg/day to 500 mg/day change was allowed. Daily UCB0942 film-coated tablets were administered orally in doses of 100 mg (50 mg bid), 200 mg (100 mg bid), 400 mg (200 mg bid), 600 mg (300 mg bid), or 800 mg (400 mg bid) for up to approximately 5 Years. Participants formed the Safety Set (SS).

Serious adverse events	UCB0942 (SS)		
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 42 (28.57%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Face injury			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fall			

subjects affected / exposed	1 / 42 (2.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Head injury				
subjects affected / exposed	1 / 42 (2.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lip injury				
subjects affected / exposed	1 / 42 (2.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Procedural nausea				
subjects affected / exposed	1 / 42 (2.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower limb fracture				
subjects affected / exposed	1 / 42 (2.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	1 / 42 (2.38%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hand fracture				
subjects affected / exposed	1 / 42 (2.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				
Myomectomy				
subjects affected / exposed	1 / 42 (2.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Therapy change				

subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Seizure			
subjects affected / exposed	3 / 42 (7.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Status epilepticus			
subjects affected / exposed	2 / 42 (4.76%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Dementia Alzheimer's type			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Memory impairment			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Seizure cluster			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			

subjects affected / exposed	2 / 42 (4.76%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	UCB0942 (SS)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 42 (76.19%)		
Investigations			
Weight increased			
subjects affected / exposed	6 / 42 (14.29%)		
occurrences (all)	6		
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	4 / 42 (9.52%)		
occurrences (all)	4		
Nervous system disorders			
Somnolence			
subjects affected / exposed	11 / 42 (26.19%)		
occurrences (all)	16		
Dizziness			
subjects affected / exposed	7 / 42 (16.67%)		
occurrences (all)	8		
Headache			
subjects affected / exposed	6 / 42 (14.29%)		
occurrences (all)	6		
Memory impairment			
subjects affected / exposed	4 / 42 (9.52%)		
occurrences (all)	4		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	9 / 42 (21.43%)		
occurrences (all)	13		
Gastrointestinal disorders			

Vomiting subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 3		
Psychiatric disorders Depressed mood subjects affected / exposed occurrences (all) Depression subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all) Irritability subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 5 3 / 42 (7.14%) 3 3 / 42 (7.14%) 3 3 / 42 (7.14%) 5		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Gastroenteritis subjects affected / exposed occurrences (all) Respiratory tract infection subjects affected / exposed occurrences (all) Urinary tract infection subjects affected / exposed occurrences (all)	6 / 42 (14.29%) 9 4 / 42 (9.52%) 4 3 / 42 (7.14%) 3 3 / 42 (7.14%) 3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 December 2015	The following major changes were introduced in Protocol Amendment 1: • A PSL 25mg tablet, which was previously unavailable, was introduced and a PSL maintenance dose of 100mg (50mg bid) was permitted to allow investigators to explore the range of doses from 100mg to 800mg per day using bid dosing. • Pharmacokinetic (PK) blood samples for the measurement of plasma concentration of PSL and metabolites were added at several visits. These samples were taken to monitor study participant compliance. Exploratory population PK analysis were performed together with evaluation of longer-term (up to 1 year) exposure-response relationships. • No tapering from the EP0069 dose before the first dose was administered in EP0073 was specified. • If the study participant had active suicidal ideation with a specific plan as indicated by a positive response ("Yes") to Question 5 of the "Since Last Visit" version of the Columbia-Suicide Severity Rating Scale (C-SSRS), the study participant was required to be referred immediately to a Mental Healthcare Professional and must have been withdrawn from the study.
14 November 2016	The following changes were introduced in Protocol Amendment 2: • The protocol information pertaining to potential drug-induced liver injury (PDILI) (exclusion criteria, withdrawal criteria, AEs of special interest, and assessment of safety) was updated based on new standard language, which was applied across all protocols at UCB. Note that these additions did not reflect a change in the known safety of the compound. • The estimate of the approximate number of study participants from EP0069 who would be included in EP0073 was increased to approximately 40. • Additional contraceptive requirements for the partners of male study participants were removed (based on nonclinical data).
09 November 2017	The primary purpose of this substantial amendment was to change the frequency for the ECG assessments after Year 2. Of note, no study participants had reached this milestone at the time of this protocol amendment, and therefore no impact on the safety analysis was expected. In addition, following the annual revision of the investigator's Brochure 2017 for PSL, the following prohibited concomitant medications were added in this protocol: strong CYP2C19 inhibitors, strong CYP2C19 inducers, and CYP2C19 sensitive substrates. As the recruitment for EP0073 had completed, study participants who were already taking these medications prior to Amendment 3, may have continued to do so, but under close monitoring. The other major changes in this amendment were as follows: • A study participant with a benefit-risk ratio of 0 to 4 (on a scale from 0 to 10) was required to be withdrawn from the study. • AEs of special interest were required to be immediately reported. • The Pharmacokinetic Per-Protocol Set (PK-PPS) that was used for the PK analysis was defined.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported