



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 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.

| 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 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 ^[2] |
|-----------------|---|

End point description:

A 75% responder is defined as a participant with a $\geq 75\%$ 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 $\times 100$. 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:

[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 >3-6) over the Evaluation Period

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

End point description:

A 75% responder is defined as a participant with a $\geq 75\%$ 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 $\times 100$. 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:

[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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 75\%$ 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 $\times 100$. 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 >39-42) over the Evaluation Period

| | |
|-----------------|--|
| End point title | 75% Responder Rate by 3-month interval (Month >39-42) over the Evaluation Period ^[15] |
|-----------------|--|

End point description:

A 75% responder is defined as a participant with a $\geq 75\%$ 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 $\times 100$. 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:

[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 | 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 ^[16] |
|-----------------|--|

End point description:

A 75% responder is defined as a participant with a $\geq 75\%$ 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 $\times 100$. 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:

[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 | 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 >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 $\geq 75\%$ 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 $\times 100$. 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 >48-51) over the Evaluation Period

| | |
|-----------------|--|
| End point title | 75% Responder Rate by 3-month interval (Month >48-51) over the Evaluation Period ^[18] |
|-----------------|--|

End point description:

A 75% responder is defined as a participant with a $\geq 75\%$ 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 $\times 100$. 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:

[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 | 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 ^[19] |
|-----------------|--|

End point description:

A 75% responder is defined as a participant with a $\geq 75\%$ 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 $\times 100$. 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:

[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 | 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 >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 $\geq 75\%$ 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 $\times 100$. 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 $\geq 50\%$ 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 $\times 100$. 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) | 3 / 42 (7.14%) 5 | | |
| Depression subjects affected / exposed occurrences (all) | 3 / 42 (7.14%) 3 | | |
| Insomnia subjects affected / exposed occurrences (all) | 3 / 42 (7.14%) 3 | | |
| Irritability subjects affected / exposed occurrences (all) | 3 / 42 (7.14%) 5 | | |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) | 6 / 42 (14.29%) 9 | | |
| Gastroenteritis subjects affected / exposed occurrences (all) | 4 / 42 (9.52%) 4 | | |
| Respiratory tract infection subjects affected / exposed occurrences (all) | 3 / 42 (7.14%) 3 | | |
| Urinary tract infection subjects affected / exposed occurrences (all) | 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 | <p>The following major changes were introduced in Protocol Amendment 1:</p> <ul style="list-style-type: none">• 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 | <p>The following changes were introduced in Protocol Amendment 2:</p> <ul style="list-style-type: none">• 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 | <p>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.</p> <p>The other major changes in this amendment were as follows:</p> <ul style="list-style-type: none">• 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