Clinical trial results:
An Open-Label, Multicenter, Extension Study to Evaluate the Safety and Efficacy of Padsevonil as Adjunctive Treatment of Focal-Onset Seizures in Adult Subjects with Drug-Resistant Epilepsy

Summary

EudraCT number	2017-003241-26
Trial protocol	GB DE HU ES CZ BG FR LT BE PT EE NL DK AT GR FI NO SE HR IT RO
Global end of trial date	22 December 2020

Results information

Result version number	v1 (current)
This version publication date	16 December 2021
First version publication date	16 December 2021

Trial information

Trial identification

Sponsor protocol code	EP0093

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03370120
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	19 January 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 December 2020
Global end of trial reached?	Yes
Global end of trial date	22 December 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the long-term safety and tolerability of padsevonil administered at individualized doses as adjunctive treatment for subjects with focal-onset seizures and drug-resistant epilepsy.

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Background therapy as permitted in the protocol.

Evidence for comparator: -

Actual start date of recruitment	27 August 2018
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	Australia: 14
Country: Number of subjects enrolled	Belgium: 12
Country: Number of subjects enrolled	Bosnia and Herzegovina: 4
Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Croatia: 1
Country: Number of subjects enrolled	Czechia: 24
Country: Number of subjects enrolled	Denmark: 10
Country: Number of subjects enrolled	Estonia: 4
Country: Number of subjects enrolled	Finland: 2
Country: Number of subjects enrolled	France: 20
Country: Number of subjects enrolled	Germany: 36
Country: Number of subjects enrolled	Greece: 2
Country: Number of subjects enrolled	Hungary: 12
Country: Number of subjects enrolled	Italy: 20
Country: Number of subjects enrolled	Japan: 33
Country: Number of subjects enrolled	Lithuania: 9
Country: Number of subjects enrolled	Mexico: 5
Country: Number of subjects enrolled	Poland: 32
Country: Number of subjects enrolled	Romania: 1
Country: Number of subjects enrolled	Serbia: 1

Country: Number of subjects enrolled	Slovakia: 4
Country: Number of subjects enrolled	Spain: 50
Country: Number of subjects enrolled	Turkey: 10
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	United States: 41
Country: Number of subjects enrolled	Bulgaria: 44
Country: Number of subjects enrolled	Ireland: 1
Worldwide total number of subjects	406
EEA total number of subjects	284

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)	395
From 65 to 84 years	11
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll study participants in August 2018 and concluded in December 2020.

Pre-assignment

Screening details:

Participant Flow refers to the Safety Set. Participants who had completed a padsevonil (PSL) parent study (EP0091 [NCT03373383] or EP0092 [NCT03739840]) were enrolled 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	Padsevonil

Arm description:

Participants received padsevonil tablets at a dose of 100 milligrams/day (mg/day) to 800 mg/day up to approximately 2 years.

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

Dosage and administration details:

Participants received padsevonil tablets at a dose of 100 mg/day to 800 mg/day up to approximately 2 years.

Number of subjects in period 1	Padsevonil
Started	406
Completed	0
Not completed	406
The trial has been suspended	3
Premature study closure	2
Because the clinical trial ended halfway	4
Study stopped by sponsor	2
Sponsor prematurely terminated this study	2
PI decision poor compliance from participant	1
Adverse event, non-fatal	24
Study was terminated by parent company UCB	2
Sponsor study closure	10

Discontinuation of drug development	3
The study was interrupted by sponsor	4
Premature program termination	1
Program closure	3
Per sponsor's instructions	1
This study is ended early	1
Discontinuation of the study	5
Sponsor stopped PSL development based on data	3
End of clinical trial discontinuation	1
Trial discontinued by sponsor	2
Promoter's decision	2
Padsenovil program closed	3
Study ended prematurely	1
Early termination by order of sponsor	2
The protocol was interrupted by sponsor	1
Asked by the sponsor	3
End of study per sponsor decision	2
The study was terminated prematurely by study lead	1
Sponsor decision to terminate study	63
The study was ended by the promoter	3
Decision of sponsor	6
Study ended	15
Development discontinued	5
Early termination of studies	5
Premature study close by sponsor's decision	4
Clinical trial has been cancelled	1
End of sponsor decision	1
Termination of project	1
Study terminated by sponsor	33
Sponsor decision	62
Consent withdrawn by subject	6
Trial terminated by sponsor	2
End of project	4
End of padsevonil program	2
Sponsor decision to stop the protocol	1
Program termination	55

Premature study termination	7
Promoter ended the study	3
Lost to follow-up	1
Lack of efficacy	37

Baseline characteristics

Reporting groups	
Reporting group title	Padsevonil
Reporting group description:	
Participants received padsevonil tablets at a dose of 100 milligrams/day (mg/day) to 800 mg/day up to approximately 2 years.	

Reporting group values	Padsevonil	Total	
Number of subjects	406	406	
Age Categorical Units: participants			
<=18 years	0	0	
Between 18 and 65 years	395	395	
>=65 years	11	11	
Age Continuous Units: years			
arithmetic mean	40.8		
standard deviation	± 12.5	-	
Sex: Female, Male Units: participants			
Female	231	231	
Male	175	175	

End points

End points reporting groups

Reporting group title	Padsevonil
Reporting group description:	
Participants received padsevonil tablets at a dose of 100 milligrams/day (mg/day) to 800 mg/day up to approximately 2 years.	
Subject analysis set title	Padsevonil (SS)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received PSL tablets at a dose of 100 mg/day to 800 mg/day up to approximately 2 years. Participants formed the Safety Set (SS).	
Subject analysis set title	Padsevonil (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants received PSL tablets at a dose of 100 mg/day to 800 mg/day up to approximately 2 years. Participants formed the Full Analysis Set (FAS).	

Primary: Percentage of Participants With Treatment-Emergent Adverse Events (TEAEs) reported by the participant and/or caregiver or observed by the investigator during the entire study

End point title	Percentage of Participants With Treatment-Emergent Adverse Events (TEAEs) reported by the participant and/or caregiver or observed by the investigator during the entire study[1]
End point description:	
An Adverse Event is any untoward medical occurrence in a participant or clinical investigation participant administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment. A TEAE was defined as any event that was not present prior to the initiation of the first dose of study treatment in this study or any unresolved event already present before initiation of the first dose that worsens in intensity following exposure to the treatment. The SS consisted of all enrolled participants who were administered at least 1 dose of PSL, based on the first dose date from the first administration of study medication Case Report Form (CRF).	
End point type	Primary
End point timeframe:	
From Entry Visit (Week 0) until the Safety Follow-up Visit (up to approximately 2 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: Please note that this is an open label study with only 1 treatment arm. Thus no statistical comparison is possible.

End point values	Padsevonil (SS)			
Subject group type	Subject analysis set			
Number of subjects analysed	406			
Units: percentage of participants				
number (not applicable)	72.2			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Treatment-Emergent Adverse Events (TEAEs) leading to study withdrawal

End point title	Percentage of Participants With Treatment-Emergent Adverse Events (TEAEs) leading to study withdrawal[2]

End point description:

An Adverse Event is any untoward medical occurrence in a participant or clinical investigation participant administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment. A TEAE was defined as any event that was not present prior to the initiation of the first dose of study treatment in this study or any unresolved event already present before initiation of the first dose that worsens in intensity following exposure to the treatment. The SS consisted of all enrolled participants who were administered at least 1 dose of PSL, based on the first dose date from the first administration of study medication CRF.

End point type	Primary

End point timeframe:

From Entry Visit (Week 0) until the Safety Follow-up Visit (up to approximately 2 years)

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: Please note that this is an open label study with only 1 treatment arm. Thus no statistical comparison is possible.

End point values	Padsevonil (SS)			
Subject group type	Subject analysis set			
Number of subjects analysed	406			
Units: percentage of participants				
number (not applicable)	5.2			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline (from the respective parent study [EP0091 or EP0092]) in observable focal-onset seizure frequency over the Evaluation Period

End point title	Change from Baseline (from the respective parent study [EP0091 or EP0092]) in observable focal-onset seizure frequency over the Evaluation Period[3]

End point description:

Seizure frequency refers to 28-day adjusted frequency. Observable focal-onset seizures refer to Type IAl, IB, and IC (according to the International League Against Epilepsy (ILAE) Classification of Epileptic Seizures, 1981). Focal-onset seizures include all Type I seizures. FAS consisted of all enrolled participants who were administered at least 1 dose of PSL or a partial dose of PSL and completed at least 1 seizure diary during the Evaluation Period.

End point type	Primary

End point timeframe:

From Baseline in respective parent study over the Evaluation Period (up to approximately 2 years) in this study

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: Please note that this is an open label study with only 1 treatment arm. Thus no statistical comparison is possible.

End point values	Padsevonil (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	406			
Units: seizures per 28 days				
arithmetic mean (standard deviation)	-7.73 (± 27.52)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Entry Visit (Week 0) until the Safety Follow-up Visit (up to approximately 2 years)

Adverse event reporting additional description:

A TEAE was defined as any event that was not present prior to the initiation of the first dose of study treatment in this study or any unresolved event already present before initiation of the first dose that worsens in intensity following exposure to the treatment.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Padsevonil (SS)

Reporting group description:

Participants received PSL tablets at a dose of 100 mg/day to 800 mg/day up to approximately 2 years. Participants formed the SS.

Serious adverse events	Padsevonil (SS)		
Total subjects affected by serious adverse events			
subjects affected / exposed	48 / 406 (11.82%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Phyllodes tumour			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			

Vagal nerve stimulator implantation			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hip arthroplasty			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abortion spontaneous			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Aggression			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suicide Attempt			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Mycoplasma test positive			

subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ulna fracture			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cervical radiculopathy			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	7 / 406 (1.72%)		
occurrences causally related to treatment / all	1 / 8		
deaths causally related to treatment / all	0 / 0		
Focal dyscognitive seizures			
subjects affected / exposed	2 / 406 (0.49%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Migraine			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Generalised tonic-clonic seizure			
subjects affected / exposed	5 / 406 (1.23%)		
occurrences causally related to treatment / all	1 / 8		
deaths causally related to treatment / all	0 / 0		

Partial seizures with secondary generalisation				
subjects affected / exposed	2 / 406 (0.49%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Partial seizures				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Postictal state				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	4 / 406 (0.99%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
Seizure cluster				
subjects affected / exposed	2 / 406 (0.49%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Status epilepticus				
subjects affected / exposed	5 / 406 (1.23%)			
occurrences causally related to treatment / all	3 / 5			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal discomfort				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Large intestinal haemorrhage				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Bile duct stone				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Drug Eruption				
subjects affected / exposed	1 / 406 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Drug reaction with eosinophilia and systemic symptoms				
subjects affected / exposed	2 / 406 (0.49%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvi-ureteric obstruction			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Corona virus infection			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cytomegalovirus infection			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection			

subjects affected / exposed	1 / 406 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Padsevonil (SS)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	184 / 406 (45.32%)		
Nervous system disorders			
Somnolence			
subjects affected / exposed	66 / 406 (16.26%)		
occurrences (all)	76		
Headache			
subjects affected / exposed	59 / 406 (14.53%)		
occurrences (all)	138		
Dizziness			
subjects affected / exposed	43 / 406 (10.59%)		
occurrences (all)	63		
Memory impairment			
subjects affected / exposed	21 / 406 (5.17%)		
occurrences (all)	38		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	47 / 406 (11.58%)		
occurrences (all)	56		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	23 / 406 (5.67%)		
occurrences (all)	27		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	29 / 406 (7.14%)		
occurrences (all)	42		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 October 2018	The following major changes were introduced in Protocol Amendment 1 dated 26 Oct 2018: • The original protocol allowed study participants without access to a Managed Access Plan to continue participation in EP0093 after the second year and until a Marketing Authorization was granted by any health authority for the adjunctive treatment of FOS in adults with drug-resistant epilepsy. This amendment limited the duration of participation of all study participants to 2 years. Study participants without access to a Managed Access Plan were offered the option to transfer to another study if approved by the relevant country agencies. • The number of sites increased from 150 to approximately 350. • The proposed indication statement was modified (drug-resistant was removed). • The study objectives specified that study participants had FOS as well as drug-resistant epilepsy. • In the analysis of the primary efficacy variable, the observable FOS frequency instead of the log-transformed observable FOS frequency was measured. • The "other" efficacy variable, time to discontinuation, was added. • It was specified that follow-up echocardiograms at 1 and 6 months after the last PSL intake were required. • China was added to the anticipated regions and countries in which the study was conducted. • The Schedule of Study Assessments was revised consistent with the main change in the amendment. This included a split of the EDV and EOT (called End of Study) visits into separate visits. • Valvular abnormality grading criteria, withdrawal criterion pertaining to echocardiographic findings, description of the measurements and observations included in the echocardiograms, laboratory measurements and prohibited concomitant treatments were made consistent with the feeder studies. • The prohibited concomitant treatments were revised to make them consistent with the feeder studies.
26 October 2018	Continuation of Protocol Amendment 1 • A clarification of the description of the interpretation of echocardiograms was made. The local physician was required to examine the echocardiograms for suitability for central reading and for determination if an expedited review by the central reader was required. It was made explicit that the central reader is a cardiologist. • The Treatment Satisfaction Questionnaire for Medication (TSQM)-9 was added to study assessments. • A preference was specified for the QOLIE-31-P, SSG, and HADS questionnaires to be completed by the study participants. However, assistance from the study staff or caregiver was permitted.
04 February 2020	The following major changes were introduced in Protocol Amendment 2 dated 04 Feb 2020: • The primary rationale for this global amendment was to update the name of the legal form of the Sponsor, UCB Biopharma. Belgium adopted a new Code of Companies and Associations, resulting in a mandatory change of the name of the legal form of the entity "société privée à responsabilité limitée", abbreviated "SPRL", to "société à responsabilité limitée", abbreviated "SRL". This change did not involve any change to the legal form itself, and the company name, company number and VAT number of UCB Biopharma remained the same. • A benefit risk assessment to comply with Section 6 of the ICH-GCP was added. • The specified dosage of 400mg/day as starting dose was deleted to allow more flexibility when adding further parent studies. The individual starting dose of each study participant was the one recommended at the end of the parent study.

20 May 2020	Protocol Amendment 2 Addendum A dated 20 May 2020 was introduced in Bulgaria, Finland, France, and Norway due to the exceptional circumstances of the evolving COVID-19 pandemic. UCB proposed to implement measures to reduce the impact on the local health care provision and reduce the inherent risk of study driven hospital/site visits. For details on the visit schedule, drug accountability, and Investigational Medicinal Product (IMP) distribution under exceptional circumstances, see Protocol Amendment 2 Addendum A.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported