

EU Results Form

Trial Information

A. Trial Identification

Full title of the trial

A Multicenter, Open-Label, Prospective Study with an Extension Phase to Evaluate the Efficacy and Safety of Perampanel Monotherapy in Untreated Subjects with Focal Onset Seizures (FOS) with or Without Focal to Bilateral Tonic-Clonic Seizures

EudraCT Number 2025-000521-14

Sponsor Protocol Code E2007-M082-606

ISRCTN Number

ClinicalTrials.gov identifier (NCT Number) NCT05533814

WHO Universal Trial Reference Number (UTRN)

Other trial identifiers	Other identifier name	Other identifier code
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B. Paediatric Regulatory Details

Is the trial part of an agreed Paediatric Investigation Plan (PIP)? No

Paediatric Investigation Plan(s) EMA Decision number of Paediatric Investigation Plan(s)

Enter the EMA paediatric Investigation plan number(s) (PIP) using the following format: EMEA-999999-PIP99-99, where 9 is a number (0-9 inclusive).

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? Yes

C. Sponsor Details

Name	Scientific Contact	Public Contact
Organisation name: Eisai Korea Inc. Street Address: Floor 10, Building Leveasant, 6 Bongeunsa-ro 86-gil, Gangnam-gu Town/City: Seoul Country: Korea, Republic of Post code: 06123	Functional contact name: EMEA Medical Information Organisation name: Eisai Korea Inc. Country code: +44 Phone Number: (0)208 600 1400 Email address: EUMedInfo@eisai.net	Functional contact name: EMEA Medical Information Organisation name: Eisai Korea Inc. Country code: +44 Phone Number: (0)208 600 1400 Email address: EUMedInfo@eisai.net

D. Results Analysis Stage

Analysis Stage Final

Date of interim/Final Analysis 2025-01-23

Is this the analysis of the primary completion data? No

Primary completion date

Global end of trial date reached? Yes

Global end of trial date 2025-01-23

Was the trial ended prematurely? No

E. General Information About Trial

Main objective of Trial

The main objective of the trial is to assess the efficacy of perampanel monotherapy in subjects having FOS with or without untreated focal to bilateral tonic-clonic seizures (FBTCS), based on the seizure-free rate during the maintenance period of the Core Study.

The actual start date of recruitment must be the current date or a date in the past.

Actual Start date of Recruitment 2022-10-19

Long term follow up planned? No

Long term follow up rationale

Long term follow up duration

Independent data monitoring committee (IDMC) involvement? No

Protection of trial subjects

This study was performed in full compliance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and all applicable local Good Clinical Practice (GCP) and regulations. This study is to be conducted in compliance with the protocol and in compliance with the EU Clinical Trial Regulation (CTR). All required study documentation is archived as required by regulatory authorities.

Background therapy

Evidence of comparator(s)

F. Population of Trial Subjects

Subject number per country

Country	Actual number of subjects enrolled
Korea, Republic of	120
Total: worldwide	120
Total: EEA	0

Age group breakdown for Trial

Age Range	Actual number of subjects enrolled
In Utero	0
Pre-term newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	18
Adolescents (12-17 years)	8
Adults (18-64 years)	75
From 65 years	
Elderly (From 65-84 years)	19
Elderly 85 years and over	0

Age Range	Actual number of subjects enrolled
Total	120

Subject Disposition

Subject Disposition

Recruitment Details Subjects took part in the study at 10 investigative sites in Korea from 19 October 2022 to 23 January 2025.

Pre-Assignment

Screening Details A total of 125 subjects were screened, of which 120 were treated in the core study which included Pretreatment Phase, Treatment Phase [Titration Period (8 weeks) and Maintenance Period (24 weeks)] and 64 were treated in the extension phase.

Pre-Assignment Period

Periods

Core Study (36 weeks)

Blinding Implementation Details:

Is this the baseline period? true

Mutually exclusive arms? true

Non-Mutual Exclusive Number of Subjects:

Allocation: Non-Randomised-Controlled

Blinding Used: Not-blind

Roles Blinded:

Started

Core Study: Perampanel (Experimental) During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject’s clinical response and tolerability.	
120	Total (=sum per row) 120 (calculated)

Safety Analysis Set 1 (SAS1)

Core Study: Perampanel (Experimental) During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject’s clinical response and tolerability.	
120 The SAS1 included subjects who received at least one dose of the investigational product and had at least one post-dose safety assessment.	Total (=sum per row) 120 (calculated)

Full Analysis Set 1 (FAS 1)

Core Study: Perampanel (Experimental)

During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject’s clinical response and tolerability.

Total
(=sum per
row)

120 The FAS1 included subjects who received at least one dose of the investigational product and had at least one post-dose efficacy assessment.	120 (calculated)
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Completed

Core Study: Perampanel (Experimental)

During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject’s clinical response and tolerability.

Total
(=sum per
row)

73	73 (calculated)
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Reasons Not Completed

Other Reason: Other

Core Study: Perampanel (Experimental)

During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of

Total
(=sum per
row)

investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject's clinical response and tolerability.

2	2 (calculated)
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Protocol Violation

Core Study: Perampanel (Experimental)

During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject's clinical response and tolerability.

Total
(=sum per
row)

3	3 (calculated)
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Lack of Efficacy

Core Study: Perampanel (Experimental)

During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject's clinical response and tolerability.

Total
(=sum per
row)

4	4 (calculated)
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Consent withdrawn by subject

Core Study: Perampanel (Experimental)

During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject's clinical response and tolerability.

Total
(=sum per
row)

21	21 (calculated)
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Lost to Follow-up

Core Study: Perampanel (Experimental)

During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject's clinical response and tolerability.

Total
(=sum per
row)

3	3 (calculated)
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Adverse event, non-fatal

Core Study: Perampanel (Experimental)

During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject's clinical response and tolerability.

Total
(=sum per
row)

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14	14 (calculated)
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Reasons Joined

Products

Arm	Product Name	Product Code	Product Other Name	Dosage and Administration Details	Pharmaceutical Forms	Routes of Administration
Core Study: Perampanel	Perampanel		Fycompa	Perampanel tablet administered orally once daily for up to 32 weeks (8-week Titration Period and 24-week Maintenance Period).	Tablet	Oral use

Extension Phase (24 weeks)

Blinding Implementation Details:

Is this the baseline period?false

Mutually exclusive arms?true

Non-Mutual Exclusive Number of Subjects:

Allocation:Non-Randomised-Controlled

Blinding Used:Not-blind

Roles Blinded:

Started

Extension Phase: Perampanel (Experimental) Subjects who completed the Core Study continued their monotherapy in the Extension Phase, at the dose level achieved at the end of the maintenance period of Core Study. At the discretion of investigators, multiple dose adjustments were allowed based on the subject's clinical response and tolerability.		Total (=sum per row)
65		65 (calculated)

Safety Analysis Set 2 (SAS2)

Extension Phase: Perampanel (Experimental) Subjects who completed the Core Study continued their monotherapy in the Extension Phase, at the dose level achieved at the end of the maintenance period of Core Study. At the discretion of investigators, multiple dose adjustments were allowed based on the subject's clinical response and tolerability.		Total (=sum per row)
64	The SAS2 included subjects who received at least one dose of the investigational product after Visit 6 (Week 32) and had at least one post-dose safety assessment.	64 (calculated)

Full Analysis Set 2 (FAS 2)

Extension Phase: Perampanel (Experimental) Subjects who completed the Core Study continued their monotherapy in the Extension Phase, at the dose level achieved at the end of the maintenance period of Core Study. At the discretion of investigators, multiple dose adjustments were allowed based on the subject's clinical response and tolerability.		Total (=sum per row)
64	The FAS2 included subjects who received at least one dose of the investigational product after Visit 6 (Week 32) and had at least one post-dose efficacy assessment	64 (calculated)

Completed

Extension Phase: Perampanel (Experimental)	
Subjects who completed the Core Study continued their monotherapy in the Extension Phase, at the dose level achieved at the end of the maintenance period of Core Study. At the discretion of investigators, multiple dose adjustments were allowed based on the subject's clinical response and tolerability.	
Total (=sum per row)	
57	57 (calculated)

Reasons Not Completed

Other Reason: Other

Extension Phase: Perampanel (Experimental)	
Subjects who completed the Core Study continued their monotherapy in the Extension Phase, at the dose level achieved at the end of the maintenance period of Core Study. At the discretion of investigators, multiple dose adjustments were allowed based on the subject's clinical response and tolerability.	
Total (=sum per row)	
5	5 (calculated)

Lack of Efficacy

Extension Phase: Perampanel (Experimental)	
Subjects who completed the Core Study continued their monotherapy in the Extension Phase, at the dose level achieved at the end of the maintenance period of Core Study. At the discretion of investigators, multiple dose adjustments were allowed based on the subject's clinical response and tolerability.	
Total (=sum per row)	
1	1 (calculated)

Consent withdrawn by subject

Extension Phase: Perampanel (Experimental)

Subjects who completed the Core Study continued their monotherapy in the Extension Phase, at the dose level achieved at the end of the maintenance period of Core Study. At the discretion of investigators, multiple dose adjustments were allowed based on the subject’s clinical response and tolerability.

Total
(=sum per
row)

2	2 (calculated)
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Reasons Joined

Products

Arm	Product Name	Product Code	Product Other Name	Dosage and Administration Details	Pharmaceutical Forms	Routes of Administration
Extension Phase: Perampanel	Perampanel		Fycompa	Perampanel tablet administered orally once daily Week 32 to Week 56.	Tablet	Oral use

Baseline Characteristics

Baseline Characteristics Information

The baseline Period is : Core Study (36 weeks)

How are baseline characteristics being reported?

Per Arm in the baseline period

Subject Analysis Sets

Reporting Groups

Reporting Group Title	Number of subjects	Description	Options
Core Study: Perampanel	120	During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to 8 mg according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32. At the discretion of investigators, dose adjustments were allowed based on the subject's clinical response and tolerability.	

Age Characteristics

Title: Age Categorical

Description:

Unit: Subjects

Reporting Group Values	Core Study: Perampanel	Total
Overall number of baseline subjects	120	120 (calculated)
Total	0 (calculated)	0 (calculated)

Title: Age Continuous

Description:

Unit: years

Central Tendency Type:Arithmetic Mean

Dispersion Type: Standard Deviation

Reporting Group Values

Core Study: Perampanel

	Arithmetic Mean	Standard Deviation
Unit of measure (years)	39.98	22.71

Gender Characteristics

Title: Gender Categorical

Description:

Unit: Subjects

Reporting Group Values

Core Study: Perampanel

Total

Overall number of baseline subjects	120	120
Female	54	54
Male	66	66

Study Categorical Characteristics

Study Continuous Characteristics

End Points

Reporting Groups

Periods	Arms
Core Study (36 weeks)	Core Study: Perampanel
Extension Phase (24 weeks)	Extension Phase: Perampanel

End Points

Primary: Percentage of Subjects who Achieved Seizure Freedom During the 24-weeks Maintenance Period

Countable or measurable?	Measurable
Description:	A seizure was a brief episode of signs or symptoms due to abnormal excessive or synchronous neuronal activity in the brain. Subjects not experiencing seizures during the 24-week maintenance period were considered to achieve seizure freedom. Full Analysis Set 1 included subjects who received the investigational product at least once and had at least one post-dose efficacy assessment. Here " number of subjects analyzed" signifies subjects who were evaluable for this endpoint.
Time Frame:	Up to 24 weeks
Measure Type:	Number
Precision/Dispersion Type:	Confidence Interval
Units:	percentage of subjects
Percentage:	95

Core Study (36 weeks)**Core Study: Perampanel**

Number of subjects that started the Arm:	120
Number of Subjects Analyzed:	66
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

	Number	Confidence Interval (95%)
	77.27	65.30 to 86.69

Secondary: Percentage of Subjects who Achieved Seizure Freedom During the Total 48-weeks Treatment Period (24-weeks Maintenance Period Plus 24-weeks Extension Phase)**Countable or measurable?**

Measurable

Description:

A seizure was a brief episode of signs or symptoms due to abnormal excessive or synchronous neuronal activity in the brain. Full Analysis Set 2 included subjects who received the investigational product at least once after Visit 6 (Week 32) and had at least one post-dose efficacy assessment. Here "number of subjects analyzed" signifies subjects who were evaluable for this endpoint.

Time Frame:

From Week 8 to Week 56 (up to 48 weeks)

Measure Type:

Number

Precision/Dispersion Type:

Confidence Interval

Units:

percentage of subjects

Percentage:

95

Arm Reporting Groups

Extension Phase (24 weeks)

Extension Phase: Perampanel

Number of subjects that started the Arm:	65
Number of Subjects Analyzed:	44
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

	Number	Confidence Interval (95%)
	79.55	64.70 to 90.20

Secondary: Percentage of Subjects With at Least 50 Percent (%) and 75% Reduction in Seizure Frequency During the 24-weeks Maintenance Period

Countable or measurable?

Measurable

Description:

The percentage of subjects who achieved at least 50% and 75% reduction from baseline in the frequency of focal onset seizures during the maintenance period were reported. Full Analysis Set 1 included subjects who received the investigational product at least once and had at least one post-dose efficacy assessment. Here "number of subjects analyzed" signifies subjects who were evaluable for this endpoint.

Time Frame:

Up to 24 weeks

Measure Type:

Number

Precision/Dispersion Type:

Confidence Interval

Units:

percentage of subjects

Percentage: 95

Arm Reporting Groups

Core Study (36 weeks)

Core Study: Perampanel

Number of subjects that started the Arm:	120
Number of Subjects Analyzed:	66
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

	Number	Confidence Interval (95%)
50% Reduction	87.88	77.51 to 94.62
75% Reduction	84.85	73.90 to 92.49

Secondary: Percentage of Subjects
With at Least 50% and 75%
Reduction in Seizure Frequency
During the 24-weeks Extension Phase

Countable or measurable? Measurable

Description: The percentage of subjects who achieved at least 50% and 75% reduction from baseline in the frequency of focal onset seizures during the extension phase were reported. Full Analysis Set 2 included subjects who received the investigational product at least once after Visit 6 (Week 32) and had at least one post-dose efficacy assessment. Here "number of subjects analyzed" signifies subjects who were evaluable for this endpoint.

Time Frame: Up to 24 weeks

Measure Type: Number

Precision/Dispersion Type: Confidence Interval

Units: percentage of subjects

Percentage: 95

Arm Reporting Groups

Extension Phase (24 weeks)

Extension Phase: Perampanel

Number of subjects that started the Arm:	65
Number of Subjects Analyzed:	48
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

	Number	Confidence Interval (95%)
50% Reduction	91.67	80.02 to 97.68
75% Reduction	87.50	74.75 to 95.27

Secondary: Median Percent Change From Baseline in Seizure Frequency per 28 Days at the End of 8 Weeks Titration Period

Countable or measurable? Measurable

Description: Median percentage change from baseline in seizure frequency was calculated by dividing the difference between median focal onset seizure frequency per 28 days and median focal onset seizure frequency per 28 days at Visit 1 by the median focal onset seizure frequency per 28 days at Visit 1 and multiplied by 100. Full Analysis Set 1 included subjects who received the investigational product at least once and had at least one

post-dose efficacy assessment. Here "number of subjects analyzed" signifies subjects who were evaluable for this endpoint. 99999 signifies that full range data was not evaluated.

Time Frame: Baseline up to 8 weeks

Measure Type: Median

Precision/Dispersion Type: Full Range (min-max)

Units: percent change

Percentage: 95

Arm Reporting Groups

Core Study (36 weeks)

Core Study: Perampanel

Number of subjects that started the Arm:	120
Number of Subjects Analyzed:	78
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

	Median	Full Range (min-max)
	-100.00	-99999 to 99999

Secondary: Median Percent Change
From Baseline in Seizure Frequency
per 28 days at the End of 24 Weeks
Maintenance Period

Countable or measurable? Measurable

Description: Median percentage change from baseline in seizure frequency was calculated by dividing the difference between median focal onset seizure frequency per 28 days and median focal onset seizure frequency per 28 days at Visit 1 by the median focal onset seizure frequency per 28 days at Visit 1 and multiplied by 100. Full Analysis Set 1 included subjects who received the investigational product at least once and had at least one post-dose efficacy assessment. Here "number of subjects analyzed" signifies subjects who were evaluable for this endpoint. 99999 signifies that full range data was not evaluated.

Time Frame: Baseline up to 24 weeks

Measure Type: Median

Precision/Dispersion Type: Full Range (min-max)

Units: percent change

Percentage:

Arm Reporting Groups

Core Study (36 weeks)
Core Study: Perampanel

Number of subjects that started the Arm:	120
Number of Subjects Analyzed:	66
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

	Median	Full Range (min-max)
	-100.00	-99999 to 99999

Secondary: Median Percent Change From Baseline in Seizure Frequency per 28 days at the End of 24 Weeks Extension Phase

Countable or measurable?
Measurable

Description:

Median percentage change from baseline in seizure frequency was calculated by dividing the difference between median focal onset seizure frequency per 28 days and median focal onset seizure frequency per 28 days at Visit 1 by the median focal onset seizure frequency per 28 days at Visit 1 and multiplied by 100. Full Analysis Set 2 included subjects who received the investigational product at least once after Visit 6 (Week 32) and had at least one post-dose efficacy assessment. Here "number of subjects analyzed" signifies subjects who were evaluable for this endpoint. 99999 signifies that full range data was not evaluated.

Time Frame:
Baseline up to 24 weeks

Measure Type:
Median

Precision/Dispersion Type:
Full Range (min-max)

Units:
percent change

Percentage:

Arm Reporting Groups

Extension Phase (24 weeks)

Extension Phase: Perampanel

Number of subjects that started the Arm:	65
Number of Subjects Analyzed:	48
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

	Median	Full Range (min-max)
	-100.00	-99999 to 99999

Secondary: Percentage of Subjects Remaining on Perampanel Treatment at the end of Maintenance Period

Countable or measurable?	Measurable
Description:	The retention rate was defined as the percentage of subjects remaining on perampanel treatment at the end of maintenance period after the initiation of treatment. Safety Analysis Set 1 included subjects who received the investigational product at least once and had at least one post-dose safety assessment. Here "number of subjects analyzed" signifies subjects who were evaluable for this endpoint.
Time Frame:	Up to 24 weeks
Measure Type:	Number
Precision/Dispersion Type:	Confidence Interval
Units:	percentage of subjects
Percentage:	95

Arm Reporting Groups

Core Study (36 weeks)
Core Study: Perampanel

Number of subjects that started the Arm:	120
Number of Subjects Analyzed:	80
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

	Number	Confidence Interval (95%)
	87.50	78.21 to 93.84

Secondary: Percentage of Subjects Remaining on Perampanel Treatment at the end of Extension Phase

Countable or measurable?	Measurable
Description:	The retention rate was defined as the percentage of subjects remaining on perampanel treatment at the end of extension phase after the initiation of treatment. Safety Analysis Set 2 included subjects who received the investigational product at least once after Visit 6 (Week 32) and had at least one post-dose safety assessment. Here "number of subjects analyzed" signifies subjects who were evaluable for this endpoint.
Time Frame:	Up to 24 weeks
Measure Type:	Number
Precision/Dispersion Type:	Confidence Interval
Units:	percentage of subjects
Percentage:	95

Arm Reporting Groups

Extension Phase (24 weeks)		
Extension Phase: Perampanel		
Number of subjects that started the Arm:	65	
Number of Subjects Analyzed:	58	
Comment: (The comment is mandatory when the number of subjects analysed is zero)		
	Number	Confidence Interval (95%)
	84.48	72.58 to 92.65

Secondary: Number of Subjects With One or More Treatment-emergent

Adverse Events (TEAEs) at the End of 8 Weeks Titration Period

Countable or measurable? Countable

Description: A TEAE was defined as an adverse event (AE) that emerged during treatment, having been absent at pretreatment (baseline); or reemerged during treatment, having been present at pretreatment (Baseline) but stopped before treatment; or worsened in severity during treatment relative to the pretreatment state, when the AE was continuous. Abnormal changes in vital signs and clinically significant laboratory values were recorded as AEs. SAS 1 for titration period included subjects who received the investigational product at least once and had at least one post-dose safety assessment.

Time Frame: From date of first administration of study drug up to end of titration period (up to 8 weeks)

Units: subjects

Percentage:

Arm Reporting Groups

Core Study (36 weeks)

Core Study: Perampanel

Number of subjects that started the Arm:	120
Number of Subjects Analyzed:	120
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

Countable

	73
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Secondary: Number of Subjects With One or More Treatment-emergent

Adverse Events (TEAEs) at the End of 24 Weeks Maintenance Period

Countable or measurable?

Countable

Description:

A TEAE was defined as an adverse event (AE) that emerged during treatment, having been absent at pretreatment (baseline); or reemerged during treatment, having been present at pretreatment but stopped before treatment; or worsened in severity during treatment relative to the pretreatment state, when the AE was continuous. Abnormal changes in vital signs and clinically significant laboratory values were recorded as AEs. SAS1 for maintenance period included subjects who received the investigational product at least once and had at least one post-dose safety assessment.

Time Frame:

From date of first administration of study drug in the maintenance period to end of maintenance period (up to 24 weeks)

Units:

subjects

Percentage:

Arm Reporting Groups

Core Study (36 weeks)

Core Study: Perampanel

Number of subjects that started the Arm:	120
Number of Subjects Analyzed:	120
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

Countable

	32
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Secondary: Number of Subjects With One or More Treatment-emergent

Adverse Events (TEAEs) at the End of 24 Weeks Extension Phase

Countable or measurable? Countable

Description: A TEAE was defined as an adverse event (AE) that emerged during treatment, having been absent at pretreatment (baseline); or reemerged during treatment, having been present at pretreatment but stopped before treatment; or worsened in severity during treatment relative to the pretreatment state, when the AE was continuous. Abnormal changes in vital signs and clinically significant laboratory values were recorded as AEs. SAS2 for extension period included subjects who received the investigational product at least once in the extension phase and had at least one post-dose safety assessment.

Time Frame: From date of first administration of study drug in the extension phase to end of extension phase (up to 24 weeks)

Units: subjects

Percentage:

Arm Reporting Groups

Extension Phase (24 weeks)

Extension Phase: Perampanel

Number of subjects that started the Arm:	65
Number of Subjects Analyzed:	64
Comment: (The comment is mandatory when the number of subjects analysed is zero)	

Countable

	21
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Adverse Events

Adverse Events

Adverse Events Information

Timeframe for adverse event reporting

From date of first administration of study drug up in core study part to last dose of study drug in extension phase (up to 60 weeks)

Adverse events reporting additional description

Core: SAS 1 = subjects who had investigational product (IP) at least once and had at least one post-dose safety assessment. Extension: SAS 2 = subjects who had IP at least once after Visit 6 (Week 32) and had at least one post-dose safety assessment. Abnormal changes in vital signs and clinically significant laboratory values were recorded as AEs.

Assessment Type Systematic

Frequency threshold for reporting non-serious adverse events: 5

Dictionary name MedDRA

Dictionary name - if other

Dictionary version 28.0

Adverse Events Reporting Groups

Reporting Group Totals

Core Study: Perampanel

During the Titration Period of 8 weeks, subjects received perampanel 2 milligrams per day (mg/day) and were up-titrated in no less than 2-week intervals in increments of 2 mg up to maximum of 8 mg per day according to the discretion of investigator. Upon entering the Maintenance Period of 24 weeks, subjects received the last dose they achieved at the end of the Titration Period and continued receiving this dose once daily for up to Week 32.

At the discretion of investigators, dose adjustments were allowed based on the subject's clinical response and tolerability.

Extension Phase: Perampanel

Subjects who completed the Core Study continued their monotherapy in the Extension Phase, at the dose level achieved at the end of the maintenance period of Core Study. At the discretion of investigators, multiple dose adjustments were allowed based on the subject's clinical response and tolerability.

Total # Subjects Exposed	120	64
Total # Subjects Affected by Serious Adverse Events	3	3
Total # Subjects Affected by Non Serious Adverse Events	67	0

Total # of Deaths (all causes)	0	0
Total # of Deaths Resulting From Adverse Events	0	0

Serious Adverse Events

Reporting Groups:

Core Study: Perampanel

Extension Phase: Perampanel

Cardiac disorders

Sinus node dysfunction

Systematic

# of subjects affected	1	0
# of subjects exposed	120	64
# of occurrences (all)	1	0
# of occurrences causally related to treatment	0	0
# of fatalities	0	0
# of fatalities causally related to treatment	0	0

Hepatobiliary disorders

Cholecystitis chronic

Systematic

# of subjects affected	0	1
# of subjects exposed	120	64

# of occurrences (all)	0	1
# of occurrences causally related to treatment	0	0
# of fatalities	0	0
# of fatalities causally related to treatment	0	0

Infections and infestations

Large intestine infection

Systematic

# of subjects affected	1	0
# of subjects exposed	120	64
# of occurrences (all)	1	0
# of occurrences causally related to treatment	0	0
# of fatalities	0	0
# of fatalities causally related to treatment	0	0

Pneumonia

Systematic

# of subjects affected	0	1
# of subjects exposed	120	64
# of occurrences (all)	0	1
# of occurrences causally related to treatment	0	0
# of fatalities	0	0

# of fatalities causally related to treatment	0	0
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Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Benign ovarian tumour

Systematic

# of subjects affected	0	1
# of subjects exposed	120	64
# of occurrences (all)	0	1
# of occurrences causally related to treatment	0	0
# of fatalities	0	0
# of fatalities causally related to treatment	0	0

Nervous system disorders

Cerebral infarction

Systematic

# of subjects affected	1	0
# of subjects exposed	120	64
# of occurrences (all)	1	0
# of occurrences causally related to treatment	0	0
# of fatalities	0	0
# of fatalities causally related to treatment	0	0

Dizziness

Systematic

# of subjects affected	1	0
# of subjects exposed	120	64
# of occurrences (all)	1	0
# of occurrences causally related to treatment	1	0
# of fatalities	0	0
# of fatalities causally related to treatment	0	0

Seizure

Systematic

# of subjects affected	0	1
# of subjects exposed	120	64
# of occurrences (all)	0	1
# of occurrences causally related to treatment	0	0
# of fatalities	0	0
# of fatalities causally related to treatment	0	0

Surgical and medical procedures

Finger amputation

Systematic

# of subjects affected	1	0
# of subjects exposed	120	64
# of occurrences (all)	1	0
# of occurrences causally related to treatment	0	0
# of fatalities	0	0
# of fatalities causally related to treatment	0	0

Non Serious Adverse Events

Threshold for non-serious adverse event reporting 5% is:

Reporting Groups:

Core Study: Perampanel

Extension Phase: Perampanel

Infections and infestations

Upper respiratory tract infection

# of subjects affected	6	0
# of subjects exposed	120	64
# of occurrences (all)	7	0

Nervous system disorders

Dizziness

Systematic

# of subjects affected	56	0
# of subjects exposed	120	64
# of occurrences (all)	58	0

Headache

Systematic

# of subjects affected	13	0
# of subjects exposed	120	64
# of occurrences (all)	15	0

Somnolence

Systematic

# of subjects affected	7	0
# of subjects exposed	120	64
# of occurrences (all)	7	0

More Information

More Information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol?

No

Amendment Date

Description

Interruptions (globally)

For any interruption, the restart date must not be before the interruption date.

Were there any global interruptions to the trial?

No

Interruption Date

Description

Restart Date

Limitations and caveats

Limitations and caveats applicable to this summary of the results

Online References

Provide identifiers to retrieve publications of interest in regards to the results of this clinical trial.

Enter PubMed Identifier (PMID)

CTIS

Data fields displayed on this tab are specific to CTIS and are not included in EudraCT Results Submissions.

CTIS

CTIS ID

Additional Results Analysis Information

Additional Information about the clinical trial