



Clinical trial results: Post-Marketing Surveillance of Fycompa in Korean Patients Summary

EudraCT number	2021-006003-15
Trial protocol	Outside EU/EEA
Global end of trial date	30 June 2021

Results information

Result version number	v1 (current)
This version publication date	20 January 2022
First version publication date	20 January 2022

Trial information

Trial identification

Sponsor protocol code	E2007-M065-505
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02722590
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Eisai Korea Inc.
Sponsor organisation address	10F, Building Revesant, 6, Bongeunsa-ro 86-gil, Gangnam-gu, Seoul, Korea, Republic of, 06163
Public contact	Anna Youngji Pyo, Eisai Korea Inc., +82 10-9607-5634, y-pyo@eisaikorea.com
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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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 June 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	30 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this post-marketing surveillance was to observe the following items regarding the safety profile of Fycompa film-coated tablets and oral suspension in normal clinical practice setting: (1) Serious adverse event / adverse drug reaction profile (2) Unexpected adverse event / adverse drug reaction profile (3) Already known adverse drug reaction profile (4) Non-serious adverse event profile (5) Other information related to the product's safety and effectiveness.

Protection of trial subjects:

This study was conducted in accordance with standard operating procedures (SOPs) of the sponsor (or designee), which are designed to ensure adherence to Good Clinical Practice (GCP) guidelines as required by the following: - Principles of the World Medical Association Declaration of Helsinki (World Medical Association, 2008) - International Council on Harmonisation (ICH) E6 Guideline for GCP (CPMP/ICH/135/95) of the European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products, International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - Title 21 of the United States (US) Code of Federal Regulations (US 21 CFR) regarding clinical studies, including Part 50 and Part 56 concerning informed subject consent and Institutional Review Board (IRB) regulations and applicable sections of US 21 CFR Part 312 - European Good Clinical Practice Directive 2005/28/EC and Clinical Trial Directive 2001/20/EC for studies conducted within any European Union (EU) country. All suspected unexpected serious adverse reactions were reported, as required, to the Competent Authorities of all involved EU member states.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 July 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Korea, Republic of: 3359
Worldwide total number of subjects	3359
EEA total number of subjects	0

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)	27
Adolescents (12-17 years)	139
Adults (18-64 years)	2989
From 65 to 84 years	196
85 years and over	8

Subject disposition

Recruitment

Recruitment details:

Subjects took part in the study at 69 investigative sites in the Korea from 25 July 2016 to 30 June 2021.

Pre-assignment

Screening details:

A total of 3692 subjects were screened, out of which 3359 subjects were eligible to take part in the study and received treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Fycompa Film-coated Tablets

Arm description:

Subjects received Fycompa (Perampanel) film-coated tablets, with initial dose of 2 milligrams per day (mg/day). The dose was increased by increments of 2 mg/day at least every 2 weeks up to maximum daily dose of 12 mg/day as per approved prescribing information in a normal clinical practice setting. Subjects received treatment for up to 24 Weeks.

Arm type	Experimental
Investigational medicinal product name	Fycompa
Investigational medicinal product code	E2007
Other name	Perampanel
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Fycompa film coated tablet once daily with the maximum daily dose of 12 mg for up to 24 weeks.

Arm title	Fycompa Oral Suspension
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Arm description:

Subjects received Fycompa oral suspension once daily at an initial dose of 4 milliliters (mL). The dose was increased by 4 milliliters per day (mL/day) at greater than or equal to (\geq) 2-week intervals for 12 weeks. No subjects were treated with Fycompa oral suspension for more than 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fycompa
Investigational medicinal product code	E2007
Other name	Perampanel
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Fycompa oral suspension for 12 weeks.

Number of subjects in period 1	Fycompa Film-coated Tablets	Fycompa Oral Suspension
Started	3354	5
Safety Analysis set	3354	5
Efficacy Analysis Set	1819	0
Completed	1819	0
Not completed	1535	5
Effective dose administered for less than 12 weeks	372	5
Efficacy evaluation not performed	1163	-

Baseline characteristics

Reporting groups

Reporting group title	Fycompa Film-coated Tablets
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Reporting group description:

Subjects received Fycompa (Perampanel) film-coated tablets, with initial dose of 2 milligrams per day (mg/day). The dose was increased by increments of 2 mg/day at least every 2 weeks up to maximum daily dose of 12 mg/day as per approved prescribing information in a normal clinical practice setting. Subjects received treatment for up to 24 Weeks.

Reporting group title	Fycompa Oral Suspension
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Reporting group description:

Subjects received Fycompa oral suspension once daily at an initial dose of 4 milliliters (mL). The dose was increased by 4 milliliters per day (mL/day) at greater than or equal to (\geq) 2-week intervals for 12 weeks. No subjects were treated with Fycompa oral suspension for more than 12 weeks.

Reporting group values	Fycompa Film-coated Tablets	Fycompa Oral Suspension	Total
Number of subjects	3354	5	3359
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	23	4	27
Adolescents (12-17 years)	138	1	139
Adults (18-64 years)	2989	0	2989
From 65-84 years	196	0	196
85 years and over	8	0	8
Age Continuous Units: years			
arithmetic mean	40.92	8	-
standard deviation	± 15.41	± 3.54	-
Gender Categorical Units: subjects			
Female	1544	3	1547
Male	1810	2	1812
Race Units: Subjects			
Asian	3354	5	3359
Ethnicity Units: Subjects			
Not hispanic or Latino	3354	5	3359

End points

End points reporting groups

Reporting group title	Fycompa Film-coated Tablets
Reporting group description: Subjects received Fycompa (Perampanel) film-coated tablets, with initial dose of 2 milligrams per day (mg/day). The dose was increased by increments of 2 mg/day at least every 2 weeks up to maximum daily dose of 12 mg/day as per approved prescribing information in a normal clinical practice setting. Subjects received treatment for up to 24 Weeks.	
Reporting group title	Fycompa Oral Suspension
Reporting group description: Subjects received Fycompa oral suspension once daily at an initial dose of 4 milliliters (mL). The dose was increased by 4 milliliters per day (mL/day) at greater than or equal to (>=) 2-week intervals for 12 weeks. No subjects were treated with Fycompa oral suspension for more than 12 weeks.	

Primary: Number of Subjects With Serious Adverse Events (SAEs)

End point title	Number of Subjects With Serious Adverse Events (SAEs) ^[1]
End point description: SAE was defined as any untoward medical occurrence at any dose if it resulted in death or life-threatening AE or required inpatient hospitalization or prolongation of existing hospitalization or resulted in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions or was a congenital anomaly/birth defect. Safety analysis set included subjects who received at least one dose of the study drug and were followed-up.	
End point type	Primary
End point timeframe: From the first Fycompa (Perampanel) administration date up to 24 weeks	
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 statistical analyses were planned for this end point.	

End point values	Fycompa Film-coated Tablets	Fycompa Oral Suspension		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3354	5		
Units: subjects	78	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Unexpected Adverse Events (AEs)

End point title	Number of Subjects With Unexpected Adverse Events (AEs) ^[2]
End point description: An unexpected AE was defined as AE with a difference in nature, severity, specificity, or outcome, compared to the product licensure/safety notification of the drug. An AE was defined as any unfavorable and unintended signs (for example, abnormality in test measures), symptoms or diseases that may developed while administration and use of medicinal drugs. It does not necessarily require a causal relationship between the drug and the adverse event. Safety analysis set included subjects who received at least one dose of the study drug and were followed-up.	

End point type	Primary
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End point timeframe:

From the first Fycompa (Perampanel) administration date up to 24 weeks

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 statistical analyses were planned for this end point.

End point values	Fycompa Film-coated Tablets	Fycompa Oral Suspension		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3354	5		
Units: subjects	467	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Adverse Drug Reactions (ADRs)

End point title	Number of Subjects With Adverse Drug Reactions (ADRs) ^[3]
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End point description:

An ADR was defined as noxious and unintended responses that occurred from arbitrary doses of drug, and whose causal relationship with the drug cannot be denied. Adverse events was considered to be ADRs in case of unknown relationship in spontaneously reported adverse events. Safety analysis set included subjects who received at least one dose of the study drug and were followed-up.

End point type	Primary
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End point timeframe:

From the first Fycompa (Perampanel) administration date up to 24 weeks

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 statistical analyses were planned for this end point.

End point values	Fycompa Film-coated Tablets	Fycompa Oral Suspension		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3354	5		
Units: subjects	841	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With AEs

End point title	Number of Subjects With AEs ^[4]
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End point description:

An AE was defined as any unfavorable and unintended signs (for example, abnormality in test measures), symptoms or diseases that may developed while administration and use of medicinal drugs. It does not necessarily require a causal relationship between the drug and the adverse event. Safety analysis set included subjects who received at least one dose of the study drug and were followed-up.

End point type	Primary
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End point timeframe:

From the first Fycompa (Perampanel) administration date up to 24 weeks

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 statistical analyses were planned for this end point.

End point values	Fycompa Film-coated Tablets	Fycompa Oral Suspension		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3354	5		
Units: subjects	1094	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinical Global Impression of Change (CGI-C) Scores

End point title	Number of Subjects With Clinical Global Impression of Change (CGI-C) Scores
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End point description:

CGI-C scale was a 7-point scale used to measure a physician's global impression of a subject's clinical condition. Scale ranged from 1 to 7; where, 1=very much improved, 2=much improved, 3=minimally improved, 4=No change, 5=minimally worse, 6=much worse, and 7=very much worse. Lower score indicated improvement and higher score indicated worse condition. Efficacy analysis set included subjects who received the effective dose (the dose was increased by increments of 2 mg/day at least every 2 weeks after initiating with a dose of 2 mg) of the study drug for at least 12 weeks and who had the investigator-reported efficacy assessment outcomes. No subjects were treated with Fycompa oral suspension for more than 12 weeks. Therefore, as per efficacy analysis set, no subjects were analyzed, and data was not collected.

End point type	Secondary
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End point timeframe:

Up to 24 weeks

End point values	Fycompa Film-coated Tablets	Fycompa Oral Suspension		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1819	0 ^[5]		
Units: subjects				
Very much improved	172			
Much improved	421			
Minimally improved	660			
No change	495			
Minimally worse	59			
Much worse	12			
Very much worse	0			

Notes:

[5] - No subjects were treated with Fycompa oral suspension for more than 12 weeks.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first Fycompa (Perampanel) administration date up to 24 weeks

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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Reporting groups

Reporting group title	Fycompa Oral Suspension
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Reporting group description:

Subjects received Fycompa oral suspension once daily at an initial dose of 4 mL. The dose was increased by 4 mL/day at ≥ 2 -week intervals for 12 weeks. No subjects were treated with Fycompa oral suspension for more than 12 weeks.

Reporting group title	Fycompa Film-coated Tablets
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Reporting group description:

Subjects received Fycompa (Perampanel) film-coated tablets, with initial dose of 2 mg/day. The dose was increased by increments of 2 mg/day at least every 2 weeks up to maximum daily dose of 12 mg/day as per approved prescribing information in a normal clinical practice setting. Subjects received treatment for up to 24 Weeks.

Serious adverse events	Fycompa Oral Suspension	Fycompa Film-coated Tablets	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	78 / 3354 (2.33%)	
number of deaths (all causes)	0	4	
number of deaths resulting from adverse events	0	2	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Condition aggravated			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Breast mass			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Apnoeic attack			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum deviation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Abulia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute psychosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aggression			
subjects affected / exposed	0 / 5 (0.00%)	3 / 3354 (0.09%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	2 / 3354 (0.06%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination, auditory			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritability			
subjects affected / exposed	0 / 5 (0.00%)	2 / 3354 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Suicide attempt			
subjects affected / exposed	0 / 5 (0.00%)	4 / 3354 (0.12%)	
occurrences causally related to treatment / all	0 / 0	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Facial bones fracture			

subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			

subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Demyelination			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	3 / 3354 (0.09%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drop attacks			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Headache			

subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 5 (0.00%)	15 / 3354 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	2 / 3354 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis viral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			

subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	5 / 3354 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pyelonephritis acute			
subjects affected / exposed	0 / 5 (0.00%)	2 / 3354 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3354 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Fycompa Oral Suspension	Fycompa Film-coated Tablets	
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 5 (0.00%)	425 / 3354 (12.67%)	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	425 / 3354 (12.67%) 430	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 July 2016	Addition of subjects with PGTC (primary generalized tonic clonic) seizure in patient population.
19 May 2020	Addition of pediatric subjects over 4 years old and subjects treatment with perampanel monotherapy.
29 May 2020	Addition of oral-suspension form.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported