Exploring the Safety And Tolerability of Doses of E2007 up to a Maximum of 12 mg In Patients With Refractory Partial Seizures

This study has been completed.

Sponsor:
Eisai Co., Ltd.

Collaborator:
Eisai Limited

Information provided by (Responsible Party):
Eisai Inc. (Eisai Co., Ltd.)

ClinicalTrials.gov Identifier:
NCT00416195

First received: December 26, 2006
Last updated: June 26, 2014
Last verified: August 2013
History of Changes

Results First Received: October 23, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Epilepsy
Interventions:	Drug: E2007 Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description

Placebo	Matching placebo once daily for 16 weeks (Days 1 to 112)
Perampanel	2 mg perampanel once daily for 2 weeks (Days 1 to 14), then 4 mg perampanel once daily for 2 weeks (Days 15 to 28), then 6 mg perampanel once daily for 2 weeks (Days 29 to 42), then 8 mg perampanel once daily for 2 weeks (Days 43 to 56), then 10 mg perampanel once daily for 2 weeks (Days 57 to 70), then 12 mg perampanel once daily for 6 weeks (the last 2 weeks of the Titration Phase [Days 71 to 84] and a 4-week Maintenance Phase [Days 85 to 112])

Participant Flow: Overall Study

	Placebo	Perampanel
STARTED	10	38
COMPLETED	8	34
NOT COMPLETED	2	4
Adverse Event	1	2
Protocol Violation	1	1
Not Specified	0	1

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Placebo	Matching placebo once daily for 16 weeks (Days 1 to 112)
Perampanel	2 mg perampanel once daily for 2 weeks (Days 1 to 14), then 4 mg perampanel once daily for 2 weeks (Days 15 to 28), then 6 mg perampanel once daily for 2 weeks (Days 29 to 42), then 8 mg perampanel once daily for 2 weeks (Days 43 to 56), then 10 mg perampanel once daily for 2 weeks (Days 57 to 70), then 12 mg perampanel once daily for 6 weeks (the last 2 weeks of the Titration Phase [Days 71 to 84] and a 4-week Maintenance Phase [Days 85 to 112])
Total	Total of all reporting groups

Baseline Measures

	Placebo	Perampanel	Total
Overall Participants Analyzed [Units: Participants]	10	38	48
Age [Units: Years] Mean (Standard Deviation)	45.5 (12.05)	40.7 (11.99)	43.1 (12.02)
Gender [Units: Participants]			
Female	5	20	25
Male	5	18	23
Race/Ethnicity, Customized [1] [Units: Participants]			

Caucasian	**10**	**38**	**48**

[1] Race

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Responders During the Maintenance Phase [Time Frame: Day 85 through Day 112]

Measure Type	Primary
Measure Title	Percentage of Responders During the Maintenance Phase
Measure Description	A patient is a responder if she/he experiences a 50% or greater reduction in seizure frequency from the baseline phase.
Time Frame	Day 85 through Day 112
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population- all subjects in the Safety Population (all randomized subjects who took at least 1 dose of study drug) who had at least 2 weeks of baseline seizure frequency data and at least 1 week of seizure frequency data after baseline (LOCF - last observation carried forward)

Reporting Groups

	Description
Placebo	Matching placebo once daily for 16 weeks (Days 1 to 112)
Perampanel	2 mg perampanel once daily for 2 weeks (Days 1 to 14), then 4 mg perampanel once daily for 2 weeks (Days 15 to 28), then 6 mg perampanel once daily for 2 weeks (Days 29 to 42), then 8 mg perampanel once daily for 2 weeks (Days 43 to 56), then 10 mg perampanel once daily for 2 weeks (Days 57 to 70), then 12 mg perampanel once daily for 6 weeks (the last 2 weeks of the Titration Phase [Days 71 to 84] and a 4-week Maintenance Phase [Days 85 to 112])

Measured Values

	Placebo	**Perampanel**
Participants Analyzed [Units: Participants]	**9**	**38**
Percentage of Responders During the Maintenance Phase [Units: Percentage of Participants]		
Responders (Yes)	**44.4**	**34.2**
Non-Responders (No)	**55.6**	**65.8**

No statistical analysis provided for Percentage of Responders During the Maintenance Phase

2. Secondary: Percentage Change in the 28-day Seizure Frequency From Baseline in the Maintenance LOCF [Time Frame: Baseline, Day 85 through Day 112]

Measure Type	Secondary
Measure Title	Percentage Change in the 28-day Seizure Frequency From Baseline in the Maintenance LOCF

Measure Description	No text entered.
Time Frame	Baseline, Day 85 through Day 112
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population (LOCF)

Reporting Groups

	Description
Placebo	Matching placebo once daily for 16 weeks (Days 1 to 112)
Perampanel	2 mg perampanel once daily for 2 weeks (Days 1 to 14), then 4 mg perampanel once daily for 2 weeks (Days 15 to 28), then 6 mg perampanel once daily for 2 weeks (Days 29 to 42), then 8 mg perampanel once daily for 2 weeks (Days 43 to 56), then 10 mg perampanel once daily for 2 weeks (Days 57 to 70), then 12 mg perampanel once daily for 6 weeks (the last 2 weeks of the Titration Phase [Days 71 to 84] and a 4-week Maintenance Phase [Days 85 to 112])

Measured Values

	Placebo	**Perampanel**
Participants Analyzed [Units: Participants]	**9**	**38**
Percentage Change in the 28-day Seizure Frequency From Baseline in the Maintenance LOCF [Units: Percent change] Median (Full Range)	**-46.4** **(-81.5 to 221.0)**	**-35.4** **(-100.0 to 93.3)**

No statistical analysis provided for Percentage Change in the 28-day Seizure Frequency From Baseline in the Maintenance LOCF

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Placebo	Matching placebo once daily for 16 weeks (Days 1 to 112)
Perampanel	2 mg perampanel once daily for 2 weeks (Days 1 to 14), then 4 mg perampanel once daily for 2 weeks (Days 15 to 28), then 6 mg perampanel once daily for 2 weeks (Days 29 to 42), then 8 mg perampanel once daily for 2 weeks (Days 43 to 56), then 10 mg perampanel once daily for 2 weeks (Days 57 to 70), then 12 mg perampanel once daily for 6 weeks (the last 2 weeks of the Titration Phase [Days 71 to 84] and a 4-week Maintenance Phase [Days 85 to 112])

Serious Adverse Events

	Placebo	**Perampanel**
Total, serious adverse events		

# participants affected / at risk	1/10 (10.00%)	1/38 (2.63%)
Gastrointestinal disorders		
Colonic polyp † 1		
# participants affected / at risk	0/10 (0.00%)	1/38 (2.63%)
Nervous system disorders		
Convulsions † 1		
# participants affected / at risk	1/10 (10.00%)	0/38 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA V. 10.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Placebo	Matching placebo once daily for 16 weeks (Days 1 to 112)
Perampanel	2 mg perampanel once daily for 2 weeks (Days 1 to 14), then 4 mg perampanel once daily for 2 weeks (Days 15 to 28), then 6 mg perampanel once daily for 2 weeks (Days 29 to 42), then 8 mg perampanel once daily for 2 weeks (Days 43 to 56), then 10 mg perampanel once daily for 2 weeks (Days 57 to 70), then 12 mg perampanel once daily for 6 weeks (the last 2 weeks of the Titration Phase [Days 71 to 84] and a 4-week Maintenance Phase [Days 85 to 112])

Other Adverse Events

	Placebo	Perampanel
Total, other (not including serious) adverse events		
# participants affected / at risk	7/10 (70.00%)	15/38 (39.47%)
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	1/10 (10.00%)	2/38 (5.26%)
Infections and infestations		
Rhinitis † 1		
# participants affected / at risk	0/10 (0.00%)	2/38 (5.26%)
Metabolism and nutrition disorders		
Diabetes mellitus † 1		
# participants affected / at risk	1/10 (10.00%)	0/38 (0.00%)
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	0/10 (0.00%)	6/38 (15.79%)
Headache † 1		

# participants affected / at risk	1/10 (10.00%)	1/38 (2.63%)
Muscle contractions involuntary † 1		
# participants affected / at risk	1/10 (10.00%)	0/38 (0.00%)
Somnolence † 1		
# participants affected / at risk	0/10 (0.00%)	3/38 (7.89%)
Psychiatric disorders		
Anxiety † 1		
# participants affected / at risk	2/10 (20.00%)	0/38 (0.00%)
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	1/10 (10.00%)	1/38 (2.63%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA V. 10.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There is **NOT** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Eisai Inc.
Organization: Eisai Call Center
phone: 888-422-4743

Responsible Party: Eisai Inc. (Eisai Co., Ltd.)
ClinicalTrials.gov Identifier: NCT00416195 History of Changes
Other Study ID Numbers: E2007-G000-208
2006-003702-26 (EudraCT Number)
Study First Received: December 26, 2006
Results First Received: October 23, 2012
Last Updated: June 26, 2014
Health Authority: European Union: European Medicines Agency

TO TOP