A Study of E2007 as an Adjunctive Therapy in Levodopa Treated Parkinson's Disease Patients With Motor Fluctuations

This study has been terminated.

(Study stopped due to lack of efficacy.)

Sponsor:
Eisai Inc.

Information provided by (Responsible Party):
Eisai Inc.

ClinicalTrials.gov Identifier:
NCT00360412

First received: August 2, 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: Non-Randomized; Endpoint Classification: Safety Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Parkinson's Disease
Intervention:	Drug: E2007

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
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration

	Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 2 mg or 4 mg During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.

Participant Flow: Overall Study

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 2 mg or 4 mg During Core Study)
STARTED	**333**	**664**
COMPLETED	**0**	**2**
NOT COMPLETED	**333**	**662**
Adverse Event	**37**	**65**
Protocol Violation	**2**	**5**
Patient withdrew consent	**27**	**52**
Lack of therapeutic efficacy	**46**	**61**
Physician Decision	**2**	**4**
Not specified	**5**	**6**
Study termination by Sponsor	**214**	**469**

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
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 2 mg or 4 mg During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.
Total	Total of all reporting groups

Baseline Measures

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 2 mg or 4 mg During Core Study)	Total
Overall Participants Analyzed [Units: Participants]	**333**	**664**	**997**
Age, Customized [1] [Units: Participants]			
<65 years	**187**	**357**	**544**
>=65 years	**146**	**307**	**453**
[1] Data comes from previous double-blind core studies (E2007-E044-301) and (E2007-A001-302).			
Gender [1] [Units: Participants]			
Female	**117**	**236**	**353**
Male	**216**	**428**	**644**
[1] Data comes from previous double-blind core studies (E2007-E044-301 and E2007-A001-302). Safety Population - All subjects entering the open-label extension study who took at least 1 dose of perampanel			
Race/Ethnicity, Customized [1] [Units: Participants]			
White	**320**	**643**	**963**
Black	**3**	**4**	**7**
Asian	**4**	**2**	**6**
Other	**6**	**15**	**21**
[1] Data comes from previous double-blind core studies (E2007-E044-301 and E2007-A001-302). Safety population.			

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Change From Baseline in Total Daily OFF Time (Hours) During Open-label Extension Study [Time Frame: Baseline, Week 0, Week 4, Week 8, Week 20, Week 32, Week 44, Week 56, Week 68]

Measure Type	Primary
Measure Title	Mean Change From Baseline in Total Daily OFF Time (Hours) During Open-label Extension Study
Measure Description	OFF state is when medication has worn off and is no longer providing benefits with regard to stiffness, slowness, and tremor. This outcome measure was based on data collected through use of a patient diary.
Time Frame	Baseline, Week 0, Week 4, Week 8, Week 20, Week 32, Week 44, Week 56, Week 68
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.
Safety Population- all subjects entering the open-label extension study who took at least 1 dose of perampanel

Reporting Groups

	Description
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 2 mg or 4 mg During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.

Measured Values

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 2 mg or 4 mg During Core Study)
Participants Analyzed [Units: Participants]	**333**	**664**
Mean Change From Baseline in Total Daily OFF Time (Hours) During Open-label Extension Study [Units: Hours] Mean (Standard Deviation)		
Week 0	**-0.78 (2.158)**	**-0.85 (2.498)**
Week 4	**-1.37 (2.483)**	**-1.16 (2.632)**
Week 8	**-1.21 (2.400)**	**-1.19 (2.568)**
Week 20	**-1.11 (2.537)**	**-1.34 (2.694)**
Week 32	**-0.91 (2.663)**	**-1.38 (2.676)**
Week 44	**-0.73 (2.371)**	**-1.44 (2.470)**
Week 56	**-0.64 (2.607)**	**-0.78 (2.010)**
week 68	**-0.92 (2.239)**	**-1.05 (1.820)**

No statistical analysis provided for Mean Change From Baseline in Total Daily OFF Time (Hours) During Open-label Extension Study

2. Secondary: Mean Change From Baseline in Total Daily ON Time (Without Dyskinesias or With Non-troublesome Dyskinesias) (Hours) During Open-label Extension Study [Time Frame: Baseline, Week 0, Week 4, Week 8, Week 20, Week 32, Week 44, Week 56, Week 68]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Total Daily ON Time (Without Dyskinesias or With Non-troublesome Dyskinesias) (Hours) During Open-label Extension Study
Measure Description	ON state is when medication is providing benefits with regard to stiffness, slowness, and tremor. This outcome measure was based on data collected through use of a patient diary.
Time Frame	Baseline, Week 0, Week 4, Week 8, Week 20, Week 32, Week 44, Week 56, Week 68
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.
Safety Population

Reporting Groups

	Description
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 2 mg or 4 mg During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.

Measured Values

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 2 mg or 4 mg During Core Study)
Participants Analyzed [Units: Participants]	**333**	**664**
Mean Change From Baseline in Total Daily ON Time (Without Dyskinesias or With Non-troublesome Dyskinesias) (Hours) During Open-label Extension Study [Units: Hours] Mean (Standard Deviation)		
Week 0	**0.73 (2.389)**	**0.65 (2.567)**
Week 4	**1.02 (2.664)**	**0.98 (2.665)**
Week 8	**0.82 (2.741)**	**0.96 (2.801)**
Week 20	**0.95 (2.811)**	**1.14 (2.803)**
Week 32	**0.77 (2.716)**	**1.05 (2.695)**
Week 44	**0.60 (2.742)**	**0.98 (2.634)**
Week 56	**0.40 (2.596)**	**0.02 (2.132)**
Week 68	**0.50 (2.121)**	**0.21 (1.539)**

No statistical analysis provided for Mean Change From Baseline in Total Daily ON Time (Without Dyskinesias or With Non-troublesome Dyskinesias) (Hours) During Open-label Extension Study

3. Secondary: Mean Change From Baseline in UPDRS Part II (ADL) Score in OFF State (Hours) During Open-label Extension Study [Time Frame: Baseline, Week 0, Week, 8, Week 20, Week 32, Week 44, Week 56, Week 68]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in UPDRS Part II (ADL) Score in OFF State (Hours) During Open-label Extension Study
Measure Description	Unified Parkinson's Disease Rating Scale (UPDRS) is a standardized assessment of the symptoms and signs of Parkinson's Disease. Part II assesses activities of daily living (ADL) based on 13 items, such as speech, hygiene, and

	falling. Participants receive a score of 0-4 points per item, with a higher score indicating more severe symptoms, for a range of total possible scores of 0-52. OFF state is when medication has worn off and is no longer providing benefits with regard to stiffness, slowness, and tremor.
Time Frame	Baseline, Week 0, Week, 8, Week 20, Week 32, Week 44, Week 56, Week 68
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.
Safety Population

Reporting Groups

	Description
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 2 mg or 4 mg During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.

Measured Values

	Perampanel (Placebo During Core Study)	**Perampanel (Perampanel 2 mg or 4 mg During Core Study)**
Participants Analyzed [Units: Participants]	**333**	**664**
Mean Change From Baseline in UPDRS Part II (ADL) Score in OFF State (Hours) During Open-label Extension Study [Units: Scores on a scale] Mean (Standard Deviation)		
Week 0	**-0.36 (4.035)**	**-0.39 (4.567)**
Week 8	**-0.31 (4.752)**	**-0.60 (4.797)**
Week 20	**-0.38 (4.667)**	**-0.36 (5.152)**
Week 32	**0.07 (5.018)**	**-0.12 (5.436)**
Week 44	**-0.22 (5.217)**	**-0.25 (5.390)**
Week 56	**-1.00 (5.228)**	**0.38 (6.171)**
Week 68	**-3.00 (0)**	**2.43 (5.623)**

No statistical analysis provided for Mean Change From Baseline in UPDRS Part II (ADL) Score in OFF State (Hours) During Open-label Extension Study

4. Secondary: Mean Change From Baseline in UPDRS Part III (Motor) Score in ON State (Hours) During Open- Label Extension Study [Time

Frame: Baseline, Week 0, Week 8, Week 20, Week 32, Week 44, Week 56, Week 68]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in UPDRS Part III (Motor) Score in ON State (Hours) During Open- Label Extension Study
Measure Description	Unified Parkinson's Disease Rating Scale (UPDRS) is a standardized assessment of the symptoms and signs of Parkinson's Disease. Part III assesses motor activity, based on 14 items, such as gait, facial expression, and rigidity. Participants receive a score of 0-4 points per item, with a higher score indicating more severe symptoms, for a range of total possible scores of 0-56. ON state is when medication is providing benefits with regard to stiffness, slowness, and tremor.
Time Frame	Baseline, Week 0, Week 8, Week 20, Week 32, Week 44, Week 56, Week 68
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.
Safety Population

Reporting Groups

	Description
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 2 mg or 4 mg During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.

Measured Values

	Perampanel (Placebo During Core Study)	**Perampanel (Perampanel 2 mg or 4 mg During Core Study)**
Participants Analyzed [Units: Participants]	**333**	**664**
Mean Change From Baseline in UPDRS Part III (Motor) Score in ON State (Hours) During Open- Label Extension Study [Units: Scores on a scale] Mean (Standard Deviation)		
Week 0	**-1.92 (6.945)**	**-1.87 (7.518)**
Week 8	**-3.17 (7.712)**	**-3.08 (8.273)**
Week 20	**-2.48 (7.425)**	**-2.72 (8.521)**
Week 32	**-2.86 (8.501)**	**-2.84 (7.677)**
Week 44	**-2.23 (8.428)**	**-2.07 (9.209)**
Week 56	**-1.91 (7.770)**	**-0.84 (9.428)**
Week 68	**-7.00 (0)**	**-1.29 (6.775)**

No statistical analysis provided for Mean Change From Baseline in UPDRS Part III (Motor) Score in ON State (Hours) During Open- Label Extension Study

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events (AEs) were defined as treatment emergent in this study if the start date of the event was on or after the start of study medication in this study. Adverse events that occurred 30 days after the last dose of study drug were 'post-treatment'.
Additional Description	No text entered.

Reporting Groups

	Description
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.
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Serious Adverse Events

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 2 mg or 4 mg During Core Study)
Total, serious adverse events		
# participants affected / at risk	**33/333 (9.91%)**	**57/664 (8.58%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**0/333 (0.00%)**	**1/664 (0.15%)**
Cardiac disorders		
Angina pectoris † 1		
# participants affected / at risk	**2/333 (0.60%)**	**2/664 (0.30%)**
Atrial fibrillation † 1		
# participants affected / at risk	**2/333 (0.60%)**	**1/664 (0.15%)**
Cardiac failure † 1		
# participants affected / at risk	**1/333 (0.30%)**	**2/664 (0.30%)**
Myocardial infarction † 1		
# participants affected / at risk	**0/333 (0.00%)**	**2/664 (0.30%)**
Acute left ventricular failure † 1		

# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Cardiopulmonary failure † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Cardiovascular disorder † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Tachycardia † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Endocrine disorders		
Hyperthyroidism † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Gastrointestinal disorders		
Ileus † 1		
# participants affected / at risk	2/333 (0.60%)	0/664 (0.00%)
Inguinal hernia † 1		
# participants affected / at risk	0/333 (0.00%)	2/664 (0.30%)
Abdomina strangulated hernia † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Diarrhoea † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Duodenal obstruction † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Duodenal polyp † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Dysphagia † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Femoral hernia † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Gastric haemorrhage † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Hematemesis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Melaena † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Nausea † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Volvulus † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Vomiting † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
General disorders		
Non-cardiac chest pain † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Hepatobiliary disorders		
Cholecystitis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)

Cholelithiasis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Infections and infestations		
Pneumonia † 1		
# participants affected / at risk	1/333 (0.30%)	2/664 (0.30%)
Bronchitis † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Cellulitis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Cystitis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Intervertebral discitis † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Osteomyelitis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Postoperative wound infection † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Sepsis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Urinary tract infection † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Injury, poisoning and procedural complications		
Fall † 1		
# participants affected / at risk	2/333 (0.60%)	0/664 (0.00%)
Femoral neck fracture † 1		
# participants affected / at risk	0/333 (0.00%)	2/664 (0.30%)
Upper limb fracture † 1		
# participants affected / at risk	1/333 (0.30%)	1/664 (0.15%)
Wrist fracture † 1		
# participants affected / at risk	1/333 (0.30%)	1/664 (0.15%)
Device dislocation † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Femur fracture † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Hip fracture † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Injury † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Patella fracture † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Tendon rupture † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Thoracic vertebral fracture † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Musculoskeletal and connective tissue disorders		
† 1		

Back pain		
# participants affected / at risk	2/333 (0.60%)	0/664 (0.00%)
Musculoskeletal chest pain † 1		
# participants affected / at risk	1/333 (0.30%)	1/664 (0.15%)
Osteoarthritis † 1		
# participants affected / at risk	1/333 (0.30%)	1/664 (0.15%)
Arthritis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Kyphoscoliosis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Lumbar spinal stenosis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Osteoporosis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Chondrosarcoma † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Endometrial cancer † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Gastrointestinal tract adenoma † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Lung neoplasm malignant † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Metastatic bronchial carcinoma † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Mycosis fungoides † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Nervous system disorders		
Parkinson's disease † 1		
# participants affected / at risk	1/333 (0.30%)	4/664 (0.60%)
On and off phenomenon † 1		
# participants affected / at risk	1/333 (0.30%)	2/664 (0.30%)
Akinesia † 1		
# participants affected / at risk	1/333 (0.30%)	1/664 (0.15%)
Dyskinesia † 1		
# participants affected / at risk	2/333 (0.60%)	0/664 (0.00%)
Amnesia † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Bradykinesia † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Cerebrovascular accident † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Dizziness † 1		

# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Dystonia † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Hyperkinesia † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Hypoaesthesia † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Hypokinesia † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Ischaemic stroke † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Muscle spasticity † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Presyncope † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Radiculopathy † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Somnolence † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Syncope † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Tremor † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Psychiatric disorders		
Psychotic disorder † 1		
# participants affected / at risk	2/333 (0.60%)	1/664 (0.15%)
Depression † 1		
# participants affected / at risk	1/333 (0.30%)	1/664 (0.15%)
Hallucination † 1		
# participants affected / at risk	0/333 (0.00%)	2/664 (0.30%)
Acute Psychosis † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Aggression † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Confusional state † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Delusion † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Hallucination, visual † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Mental disorder † 1		
# participants affected / at risk	0/333 (0.00%)	1/664 (0.15%)
Mental status changes † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)
Pathological gambling † 1		
# participants affected / at risk	1/333 (0.30%)	0/664 (0.00%)

Suicidal ideation † 1		
# participants affected / at risk	**0/333 (0.00%)**	**1/664 (0.15%)**
Suicidal attempt † 1		
# participants affected / at risk	**0/333 (0.00%)**	**1/664 (0.15%)**
Reproductive system and breast disorders		
Postmenopausal haemorrhage † 1		
# participants affected / at risk	**1/333 (0.30%)**	**0/664 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Asthma † 1		
# participants affected / at risk	**1/333 (0.30%)**	**0/664 (0.00%)**
Dyspnoea † 1		
# participants affected / at risk	**0/333 (0.00%)**	**1/664 (0.15%)**
Pneumonia aspiration † 1		
# participants affected / at risk	**1/333 (0.30%)**	**0/664 (0.00%)**
Skin and subcutaneous tissue disorders		
Decubitus ulcer † 1		
# participants affected / at risk	**0/333 (0.00%)**	**1/664 (0.15%)**
Vascular disorders		
Aortic aneurysm † 1		
# participants affected / at risk	**0/333 (0.00%)**	**1/664 (0.15%)**
Hypertension † 1		
# participants affected / at risk	**0/333 (0.00%)**	**1/664 (0.15%)**
Hypertensive crisis † 1		
# participants affected / at risk	**1/333 (0.30%)**	**0/664 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events (AEs) were defined as treatment emergent in this study if the start date of the event was on or after the start of study medication in this study. Adverse events that occurred 30 days after the last dose of study drug were 'post-treatment'.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Perampanel (Placebo During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn

	from the study.
Perampanel (Perampanel 2 mg or 4 mg During Core Study)	Subjects entered this open-label extension study from the double-blind core studies (E2007-E044-301 and E2007-A001-302). Subjects started on perampanel 2mg once daily for two weeks, followed by 4mg once daily for 2 weeks (Titration Phase); Subjects then continued onto the maintenance phase of perampanel 4mg once daily for 2 weeks. Subjects that did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects that did not tolerate 2mg were withdrawn from the study.

Other Adverse Events

	Perampanel (Placebo During Core Study)	Perampanel (Perampanel 2 mg or 4 mg During Core Study)
Total, other (not including serious) adverse events		
# participants affected / at risk	**104/333 (31.23%)**	**201/664 (30.27%)**
Injury, poisoning and procedural complications		
Fall † 1		
# participants affected / at risk	**24/333 (7.21%)**	**32/664 (4.82%)**
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	**14/333 (4.20%)**	**35/664 (5.27%)**
Nervous system disorders		
Dyskinesia † 1		
# participants affected / at risk	**33/333 (9.91%)**	**72/664 (10.84%)**
On and off phenomenon † 1		
# participants affected / at risk	**42/333 (12.61%)**	**73/664 (10.99%)**
Somnolence † 1		
# participants affected / at risk	**22/333 (6.61%)**	**33/664 (4.97%)**
Psychiatric disorders		
Insomnia † 1		
# participants affected / at risk	**17/333 (5.11%)**	**37/664 (5.57%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA Version 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
Due to early termination, a limited number of subjects (only 2) completed this open-label extension study. The majority of subjects did not reach the scheduled Week 56 assessment. Many outcomes could only be analyzed to Week 68 as a result.

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.
ClinicalTrials.gov Identifier:	NCT00360412 History of Changes
Other Study ID Numbers:	E2007-G000-303 2006-002339-26 (EudraCT Number)
Study First Received:	August 2, 2006
Results First Received:	October 23, 2012
Last Updated:	June 26, 2014
Health Authority:	United States: Food and Drug Administration European Union: European Medicines Agency

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For Patients and Families | For Researchers | For Study Record Managers

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