Evaluation of the Long-term Safety, Tolerability, and Efficacy of Perampanel (E2007) as an Adjunctive Therapy in Levodopa Treated Parkinson's Disease Subjects With Motor Fluctuations

This study has been terminated.

(Study stopped due to lack of efficacy.)

Sponsor:
Eisai Limited

Information provided by (Responsible Party):
Eisai Inc. (Eisai Limited)

ClinicalTrials.gov Identifier:
NCT00505622

First received: July 9, 2007
Last updated: December 17, 2015
Last verified: November 2015
History of Changes

Results First Received: October 23, 2012

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Parkinson's Disease
Intervention:	Drug: Perampanel

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 study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not

	tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Entacapone 200mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 4mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.

Participant Flow: Overall Study

	Perampanel (Placebo During Core Study)	Perampanel (Entacapone 200mg During Core Study)	Perampanel (Perampanel 4mg During Core Study)
STARTED	121	108	96
COMPLETED	0	0	0
NOT COMPLETED	121	108	96
Adverse Event	5	6	4
Protocol Violation	1	1	0
Withdrawal by Subject	0	3	2
Study termination by sponsor	115	98	90

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 study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Entacapone 200mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.

Perampanel (Perampanel 4mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Total	Total of all reporting groups

Baseline Measures

	Perampanel (Placebo During Core Study)	Perampanel (Entacapone 200mg During Core Study)	Perampanel (Perampanel 4mg During Core Study)	Total
Overall Participants Analyzed [Units: Participants]	**121**	**108**	**96**	**325**
Age, Customized [1] [Units: Particpants]				
<65	**65**	**52**	**46**	**163**
>= 65	**56**	**56**	**50**	**162**
[1] Data comes from previous double-blind core study (E2007-G000-309). Safety Population.				
Gender [1] [Units: Participants]				
Female	**46**	**44**	**30**	**120**
Male	**75**	**64**	**66**	**205**
[1] Data comes from previous double-blind core study (E2007-G000-309). 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	**92**	**75**	**65**	**232**
Asian	**29**	**33**	**31**	**93**
[1] This baseline characteristic is for Race. Data comes from previous double-blind core study (E2007-G000-309). 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 2, Week 4, Week 8, Week 20, Follow-up]

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. All data was collected using a 3-day diary within a window of a defined visit.
Time Frame	Baseline, Week 0, Week 2, Week 4, Week 8, Week 20, Follow-up
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 study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Entacapone 200mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 4mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.

Measured Values

	Perampanel (Placebo During Core Study)	**Perampanel (Entacapone 200mg During Core Study)**	**Perampanel (Perampanel 4mg During Core Study)**
Participants Analyzed [Units: Participants]	**121**	**108**	**96**
Mean Change From Baseline in Total Daily OFF Time (Hours) During Open-label Extension Study [Units: Hours] Mean (Standard Deviation)			
Week 0	**-1.03 (2.635)**	**-1.07 (2.595)**	**-1.24 (2.643)**
Week 2	**-0.91 (2.323)**	**-1.28 (2.867)**	**-1.31 (2.779)**
Week 4	**-0.65 (2.945)**	**-1.15 (2.010)**	**-1.67 (2.438)**
Week 8	**-0.70 (2.983)**	**-1.16 (2.509)**	**-1.36 (2.324)**
Week 20	**-1.34 (2.972)**	**-1.14 (1.805)**	**-2.11 (2.163)**
Follow-up	**-0.77 (2.983)**	**-1.61 (2.435)**	**-0.94 (2.978)**

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 UPDRS Part II (ADL) Score in OFF State (Hours) During Open-label Extension Study [Time Frame: Baseline, Week 0, Week 20, Week 32]

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. 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 20, Week 32
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 study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Entacapone 200mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 4mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.

Measured Values

	Perampanel (Placebo During Core Study)	**Perampanel (Entacapone 200mg During Core Study)**	**Perampanel (Perampanel 4mg During Core Study)**
Participants Analyzed [Units: Participants]	**121**	**108**	**96**
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	**-0.84 (4.241)**	**-1.99 (4.469)**	**-1.66 (4.598)**
Week 20	**-0.12 (4.727)**	**-2.82 (4.086)**	**-2.66 (4.972)**
Week 32	**1.11 (2.667)**	**0.60 (2.408)**	**-0.67 (3.141)**

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

3. 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 20, Week 32]

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. ON state is when medication is providing benefits to stiffness, slowness, and tremor.
Time Frame	Baseline, Week 0, Week 20, Week 32
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 study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Entacapone 200mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 4mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.

Measured Values

	Perampanel (Placebo During Core Study)	**Perampanel (Entacapone 200mg During Core Study)**	**Perampanel (Perampanel 4mg During Core Study)**
Participants Analyzed [Units: Participants]	**121**	**108**	**96**
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	**-0.25 (6.874)**	**-0.64 (6.911)**	**-0.96 (6.999)**
Week 20	**0.30 (7.463)**	**-0.53 (6.950)**	**-1.63 (8.005)**
Week 32	**2.22 (5.869)**	**-2.00 (5.523)**	**7.17 (6.463)**

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

4. 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 2, Week 4, Week 8, Week 20, Follow-up]

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. All data was collected using a 3-day diary within a window of a defined visit.
Time Frame	Baseline, Week 0, Week 2, Week 4, Week 8, Week 20, Follow-up
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 study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Entacapone 200mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 4mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.

Measured Values

	Perampanel (Placebo During Core Study)	**Perampanel (Entacapone 200mg During Core Study)**	**Perampanel (Perampanel 4mg During Core Study)**
Participants Analyzed [Units: Participants]	**121**	**108**	**96**
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	**1.08 (2.820)**	**0.58 (3.004)**	**0.48 (2.773)**
Week 2	**0.30 (2.776)**	**0.80 (2.731)**	**0.91 (2.940)**
Week 4	**0.38 (2.825)**	**0.43 (2.091)**	**1.24 (2.724)**
Week 8	**0.17 (3.099)**	**0.52 (2.542)**	**0.73 (2.261)**
Week 20	**0.94 (3.535)**	**0.82 (2.231)**	**1.62 (2.351)**
Follow-up	**0.43 (3.368)**	**1.12 (2.561)**	**0.85 (3.497)**

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

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 study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
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Perampanel (Perampanel 4mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.

Serious Adverse Events

	Perampanel (Placebo During Core Study)	Perampanel (Entacapone 200mg During Core Study)	Perampanel (Perampanel 4mg During Core Study)
Total, serious adverse events			
# participants affected / at risk	**2/121 (1.65%)**	**6/108 (5.56%)**	**2/96 (2.08%)**
Cardiac disorders			
Angina Pectoris † 1			

# participants affected / at risk	0/121 (0.00%)	1/108 (0.93%)	0/96 (0.00%)
General disorders			
Chest Pain † 1			
# participants affected / at risk	0/121 (0.00%)	0/108 (0.00%)	1/96 (1.04%)
Nervous system disorders			
Dementia † 1			
# participants affected / at risk	0/121 (0.00%)	1/108 (0.93%)	0/96 (0.00%)
Parkinson's Disease † 1			
# participants affected / at risk	1/121 (0.83%)	0/108 (0.00%)	0/96 (0.00%)
Radicular Syndrome † 1			
# participants affected / at risk	0/121 (0.00%)	1/108 (0.93%)	0/96 (0.00%)
Transient Ischaemic Attack † 1			
# participants affected / at risk	0/121 (0.00%)	1/108 (0.93%)	0/96 (0.00%)
Psychiatric disorders			
Hallucination † 1			
# participants affected / at risk	0/121 (0.00%)	1/108 (0.93%)	0/96 (0.00%)
Renal and urinary disorders			
Nephrolithiasis † 1			
# participants affected / at risk	1/121 (0.83%)	0/108 (0.00%)	0/96 (0.00%)
Reproductive system and breast disorders			
Uterine Prolapse † 1			
# participants affected / at risk	0/121 (0.00%)	0/108 (0.00%)	1/96 (1.04%)
Vascular disorders			
Hypotension † 1			
# participants affected / at risk	0/121 (0.00%)	1/108 (0.93%)	0/96 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA v.11

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 study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Entacapone 200mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.
Perampanel (Perampanel 4mg During Core Study)	Subjects entered this open-label extension study from the double-blind core study (E2007-G000-309). Subjects started on perampanel 2mg once daily for 2 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 who did not tolerate the study drug at 4mg were allowed to down-titrate to 2mg. Subjects who did not tolerate 2mg were withdrawn from the study.

Other Adverse Events

	Perampanel (Placebo During Core Study)	Perampanel (Entacapone 200mg During Core Study)	Perampanel (Perampanel 4mg During Core Study)
Total, other (not including serious) adverse events			
# participants affected / at risk	**27/121 (22.31%)**	**27/108 (25.00%)**	**17/96 (17.71%)**
Nervous system disorders			
Dizziness † 1			
# participants affected / at risk	**8/121 (6.61%)**	**3/108 (2.78%)**	**4/96 (4.17%)**
Dyskinesia † 1			
# participants affected / at risk	**4/121 (3.31%)**	**6/108 (5.56%)**	**5/96 (5.21%)**
On and Off Phenomenon † 1			
# participants affected / at risk	**9/121 (7.44%)**	**12/108 (11.11%)**	**6/96 (6.25%)**
Parkinson's Disease † 1			
# participants affected / at risk	**7/121 (5.79%)**	**3/108 (2.78%)**	**1/96 (1.04%)**
Somnolence † 1			
# participants affected / at risk	**4/121 (3.31%)**	**6/108 (5.56%)**	**3/96 (3.13%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA v.11

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, no subjects completed this open-label extension study.

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 Limited)
ClinicalTrials.gov Identifier:	NCT00505622 History of Changes
Other Study ID Numbers:	E2007-G000-318 2007-000801-30 (EudraCT Number)
Study First Received:	July 9, 2007
Results First Received:	October 23, 2012
Last Updated:	December 17, 2015
Health Authority:	European Union: European Medicines Agency Singapore: Health Sciences Authority Taiwan: Department of Health Hong Kong: Department of Health South Korea: Korea Food and Drug Administration (KFDA) Israel: Ministry of Health India: Drugs Controller General of India South Africa: Medicines Control Council

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