Trial record **1 of 1** for: 093-050

Previous Study | Return to List | Next Study

Eslicarbazepine Acetate Monotherapy Long Term Study

ClinicalTrials.gov Identifier: NCT00910247

Recruitment Status: Completed
First Posted: May 29, 2009
Results First Posted: July 17, 2018
Last Update Posted: July 17, 2018

Sponsor:
Sunovion

Information provided by (Responsible Party):
Sunovion

Study Details | Tabular View | Study Results | Disclaimer
How to Read a Study Record

Study Type:	Interventional
Study Design:	Intervention Model: Single Group Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition:	Epilepsy

Intervention:	Drug: Eslicarbazepine acetate

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
Subjects that participated in either study 093-045NCT00866775) or study 093-046(NCT01091662) were eligible to participate in study 093-050

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Subjects who completed the 18-week treatment period or exited the study per protocol may be eligible to participate. Subjects who discontinued for reasons other than reaching the exit criteria may be eligible if there is no safety concern, however, subjects must have completed at least the first 3 weeks of the 18-week double-blind treatment

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Participant Flow: Overall Study

	Eslicarbazepine Acetate
STARTED	**274**
COMPLETED	**205**
NOT COMPLETED	**69**
Adverse Event	**15**

Death	**2**
Lost to Follow-up	**10**
Physician Decision	**3**
Protocol Violation	**10**
Withdrawal by Subject	**25**
Not collected	**4**

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.
full analysis set

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Baseline Measures

	Eslicarbazepine Acetate
Overall Participants Analyzed [Units: Participants]	**274**
Age [Units: Participants] Count of Participants	
<=18 years	**12** 4.4%

Between 18 and 65 years	**258** 94.2%
>=65 years	**4** 1.5%
Age [Units: Years] Mean (Standard Deviation)	**37.9 (12.70)**
Sex: Female, Male [Units: Participants] Count of Participants	
Female	**134** 48.9%
Male	**140** 51.1%
Ethnicity (NIH/OMB) [Units: Participants] Count of Participants	
Hispanic or Latino	**28** 10.2%
Not Hispanic or Latino	**246** 89.8%
Unknown or Not Reported	**0** 0.0%
Race (NIH/OMB) [Units: Participants] Count of Participants	
American Indian or Alaska Native	**2** 0.7%
Asian	**5** 1.8%
Native Hawaiian or Other Pacific Islander	**0** 0.0%
Black or African American	**22** 8.0%
White	**229** 83.6%
More than one race	**2** 0.7%
Unknown or Not Reported	**14** 5.1%
Region of Enrollment [Units: Participants]	
Canada	**3**
United States	**167**
Czechia	**27**

Ukraine	**57**
Bulgaria	**18**
Serbia	**2**

Outcome Measures

Hide All Outcome Measures

1. **Primary: Number and Percent of Subjects With Treatment Emergent Adverse Events [Time Frame: One year]**

Measure Type	Primary
Measure Title	Number and Percent of Subjects With Treatment Emergent Adverse Events
Measure Description	Number and percent of subjects with treatment emergent adverse events
Time Frame	One year

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.
The Intent-to -Treat (ITT) population consisted of all subjects who had taken any open-label study medication

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Number and Percent of Subjects With Treatment Emergent Adverse Events [Units: Participants] Count of Participants	**220**

No statistical analysis provided for Number and Percent of Subjects With Treatment Emergent Adverse Events

2. Secondary: Number and Percentage of Subjects With Potentially Clinically Significant Clinical Laboratory Evaluations [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	Number and Percentage of Subjects With Potentially Clinically Significant Clinical Laboratory Evaluations
Measure Description	Number and percentage of subjects with potentially clinically significant clinical laboratory evaluations
Time Frame	1 year

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.
The intent-to-treat (ITT) population consisted of all subjects who have taken any open-label study medication.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD

	Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Number and Percentage of Subjects With Potentially Clinically Significant Clinical Laboratory Evaluations [Units: Participants] Count of Participants	**186**

No statistical analysis provided for Number and Percentage of Subjects With Potentially Clinically Significant Clinical Laboratory Evaluations

3. Secondary: Number and Percent of Subjects With Normal Baseline Sodium Reaching Blood Sodium ≤135 mmol/L, ≤130 mmol/L, and ≤125 mmol/L [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	Number and Percent of Subjects With Normal Baseline Sodium Reaching Blood Sodium ≤135 mmol/L, ≤130 mmol/L, and ≤125 mmol/L
Measure Description	Number and percentage of subjects who had normal sodium value (i.e. >135 mEq/L) at baseline but reached <=135 mEq/L and >130 mEq/L, <=130 mEq/L and >125 mEq/L, or <=125 mEq/L at any post baseline.
Time Frame	1 year

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 subjects with baseline sodium and at least one post baseline sodium value

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**261**
Number and Percent of Subjects With Normal Baseline Sodium Reaching Blood Sodium ≤135 mmol/L, ≤130 mmol/L, and ≤125 mmol/L [Units: Participants] Count of Participants	
<=135 mEq/L and >130 mEq/L	**48**
<=130 mEq/L and >125 mEq/L	**22**
<=125 mEq/L	**4**

No statistical analysis provided for Number and Percent of Subjects With Normal Baseline Sodium Reaching Blood Sodium ≤135 mmol/L, ≤130 mmol/L, and ≤125 mmol/L

4. Secondary: Percentage of Subjects With Increase of Body Weight ≥7% [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	Percentage of Subjects With Increase of Body Weight ≥7%
Measure Description	Percentage of subjects with increase of body weight ≥7%
Time Frame	1 year

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.
The intent-to-treat (ITT) population consisted of all subjects who have taken any open-label study medication.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Percentage of Subjects With Increase of Body Weight ≥7% [Units: Percentagae of participants]	**27**

No statistical analysis provided for Percentage of Subjects With Increase of Body Weight ≥7%

5. Secondary: Number and Percentage of Subjects With Orthostatic Effects. [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	Number and Percentage of Subjects With Orthostatic Effects.
Measure Description	Number and percentage of subjects with orthostatic effects.
Time Frame	1 year

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.
The intent-to-treat (ITT) population consisted of all subjects who have taken any open-label study medication.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Number and Percentage of Subjects With Orthostatic Effects. [Units: Participants] Count of Participants	**67**

No statistical analysis provided for Number and Percentage of Subjects With Orthostatic Effects.

6. Secondary: Number and Percentage of Subjects With QTc-F Changes (in Categories) From Baseline. [Time Frame: Baseline, Month 12]

Measure Type	Secondary
Measure Title	Number and Percentage of Subjects With QTc-F Changes (in Categories) From Baseline.
Measure Description	Number and percentage of subjects by QT interval corrected using the Fridericia fomula (QTcF) categories

	Based on the numbers of subjects who had at least one post-baseline assessment, the number and percentage of subjects with QTcF values in the following categories were summarized: 1. >500 millisecond (msec) at any post-baseline timepoint but not present at baseline 2. >480 msec at any post-baseline timepoint but not present at baseline 3. >450 msec at any post-baseline timepoint but not present at baseline 4. Change from Baseline >=60 ms for at least one post-baseline measurement 5. Change from Baseline >=30 ms for at least one post-baseline measurement and <60 ms for all post-baseline measurement QT interval is a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle.
Time Frame	Baseline, Month 12

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.
The intent-to-treat (ITT) subjects with at least one post-baseline assessment

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate

Participants Analyzed	272
Number and Percentage of Subjects With QTc-F Changes (in Categories) From Baseline. [Units: Participants] Count of Participants	
>500ms at any postbaseline not present at baseli	0
>450ms at any postbaseline not present at baseline	9
>480ms at any postbaseline not present at baseline	1
CFB >=60 ms for at least one post-baseline	0
CFB>=30ms for at least one &<60ms for all PBL	42

No statistical analysis provided for Number and Percentage of Subjects With QTc-F Changes (in Categories) From Baseline.

7. Secondary: Percentage of Events in Each Classification of the Columbia Suicide Severity Rating Scale (C SSRS). [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	Percentage of Events in Each Classification of the Columbia Suicide Severity Rating Scale (C SSRS).
Measure Description	The C-SSRS is an instrument designed to systematically assess and track suicidal behavior and suicidal ideation. The C-SSRS will be completed by the Investigator or Sub-Investigator (or qualified site personnel). Suicidal ideation is collected as any occurrence of wish to be dead, non-specific active suicidal thoughts, active suicidal ideation with any methods (not plan) without intent to act, active suicidal ideation with some intent to act, without specific plan, active suicidal ideation with specific plan and intent. Suicidal behavior is collected as any occurrence of actual attempts, Non-Suicidal Self-Injurious Behavior, interrupted attempts, aborted attempts, or preparatory acts or behavior, suicidal behavior.

	Any suicidality is defined as having at least one occurrence of Suicidal Behavior or Suicidal Ideation.
Time Frame	1 year

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.
The Intent-to-Treat (ITT) population consisted of all subjects that received any open-label study medication

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Percentage of Events in Each Classification of the Columbia Suicide Severity Rating Scale (C SSRS). [Units: Percentage of events]	
Any Suicidality	**4.0**
Any suicidal behavior	**0.7**
Any suicidal ideation	**3.6**

No statistical analysis provided for Percentage of Events in Each Classification of the Columbia Suicide Severity Rating Scale (C SSRS).

8. Secondary: Time on Eslicarbazepine Acetate Monotherapy. [Time Frame: One year]

Measure Type	Secondary
Measure Title	Time on Eslicarbazepine Acetate Monotherapy.
Measure Description	The start of the monotherapy period was defined as the date of termination of all other anti-epileptic drugs while taking study medication. Time on eslicarbazepine acetate monotherapy is defined from the date of the first monotherapy dose in 093-045 or 093-046 study to the last known dose of monotherapy treatment, regardless of dose change and the time gap between the parent studies and the current study.
Time Frame	One year

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 Subjects who started the monotherapy period (Visit 6/Week 8) in 093-045 or 093-046 and did not add a non-rescue/emergency Antiepileptic drug (AED) during the start date of the monotherapy period

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**238**
Time on Eslicarbazepine Acetate Monotherapy. [Units: Days] Median (95% Confidence Interval)	**NA** [1]

[1] Median not calculable due to lack of events

No statistical analysis provided for Time on Eslicarbazepine Acetate Monotherapy.

9. Secondary: Change in Seizure Frequency From Baseline. [Time Frame: Month 12 from baseline]

Measure Type	Secondary
Measure Title	Change in Seizure Frequency From Baseline.
Measure Description	Relative (%) change in standard seizure frequency(SSF) from baseline
Time Frame	Month 12 from baseline

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.
Intent-to-treat (ITT) population consisted of all subjects who had taken any open-label study medication

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
	-66.4 **(-88.8 to -32.3)**

Change in Seizure Frequency From Baseline. [Units: Percent change] Median (Inter-Quartile Range)	

No statistical analysis provided for Change in Seizure Frequency From Baseline.

10. Secondary: Responder Rate (Percentage of Subjects With a ≥50% Reduction of Seizure Frequency From Baseline). [Time Frame: One year]

Measure Type	Secondary
Measure Title	Responder Rate (Percentage of Subjects With a ≥50% Reduction of Seizure Frequency From Baseline).
Measure Description	Responder rate (percentage of subjects with a ≥50% reduction of seizure frequency from baseline).
Time Frame	One year

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.
The intent-to-treat (ITT) population consisted of all subjects who have taken any open-label study medication.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Responder Rate (Percentage of Subjects With a ≥50% Reduction of Seizure Frequency From Baseline). [Units: Percentage of participants]	**62.4**

No statistical analysis provided for Responder Rate (Percentage of Subjects With a ≥50% Reduction of Seizure Frequency From Baseline).

11. Secondary: Percentage of Subjects That Are Seizure-free During Study [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	Percentage of Subjects That Are Seizure-free During Study
Measure Description	Percentage of subjects that are seizure-free during study
Time Frame	1 year

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.
The intent-to-treat (ITT) population consisted of all subjects who have taken any open-label study medication.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Percentage of Subjects That Are Seizure-free During Study [Units: Percentage of participants]	**7.3**

No statistical analysis provided for Percentage of Subjects That Are Seizure-free During Study

12. Secondary: Completion Rate (% of Subjects Completing the One Year Treatment) [Time Frame: One year]

Measure Type	Secondary
Measure Title	Completion Rate (% of Subjects Completing the One Year Treatment)
Measure Description	Completion rate (% of subjects completing the one year treatment)
Time Frame	One year

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.
The intent-to-treat (ITT) population consisted of all subjects who have taken any open-label study medication.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Completion Rate (% of Subjects Completing the One Year Treatment) [Units: Percentagae of participants]	**74.8**

No statistical analysis provided for Completion Rate (% of Subjects Completing the One Year Treatment)

13. Secondary: Treatment Retention Time (Time to Withdrawal Due to Lack of Efficacy or Adverse Events) [Time Frame: One year]

Measure Type	Secondary
Measure Title	Treatment Retention Time (Time to Withdrawal Due to Lack of Efficacy or Adverse Events)
Measure Description	The retention time is defined from the start of eslicarbazepine acetate monotherapy period in 093-045 or 093-046 to the last known dose of open-label eslicarbazepine acetate. The time may include taking eslicarbazepine acetate concomitantly with other anti-epileptic drugs. If a subject's termination reason(s) includes: withdrawal of consent, lost to follow-up, physician decision or other, then it was assumed the subject terminated the study due to lack of efficacy.
Time Frame	One year

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.
Intent-to-treat (ITT) subjects who started the monotherapy period in 093-045 or 093-046 (visi t6/week 8)

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**255**
Treatment Retention Time (Time to Withdrawal Due to Lack of Efficacy or Adverse Events) [Units: Days] Median (95% Confidence Interval)	**NA** [1]

[1] Median time in Days is NA so the 95% CI cannot be calculated since median not calculable due to lack of events during the 1 year open-label period.

No statistical analysis provided for Treatment Retention Time (Time to Withdrawal Due to Lack of Efficacy or Adverse Events)

14. Secondary: Change in Total Score From Baseline in 31-Item Quality of Life in Epilepsy (QOLIE-31). [Time Frame: baseline and Month 12]

Measure Type	Secondary
Measure Title	Change in Total Score From Baseline in 31-Item Quality of Life in Epilepsy (QOLIE-31).
Measure Description	Change in the overall score from baseline in 31-Item Quality of Life in Epilepsy (QOLIE-31) The QOLIE-31 overall score was obtained by using a weighted average of multi-item scale scores. The recorded responses were converted to

	0-100 point scales. The mean of the individual item scores in each subgroup were calculated, with higher converted scores reflecting better quality of life.
Time Frame	baseline and Month 12

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.
The intent-to-treat (ITT) population consisted of all subjects who have taken any open-label study medication.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Change in Total Score From Baseline in 31-Item Quality of Life in Epilepsy (QOLIE-31). [Units: Units on a scale] Mean (Standard Deviation)	**6.6 (15.29)**

No statistical analysis provided for Change in Total Score From Baseline in 31-Item Quality of Life in Epilepsy (QOLIE-31).

15. Secondary:

Change in Total Score From Baseline in Montgomery-Asberg Depression Rating Scale (MADRS). [Time Frame: 1 year]

Measure Type	Secondary
Measure Title	Change in Total Score From Baseline in Montgomery-Asberg Depression Rating Scale (MADRS).
Measure Description	The total score of MADRS is defined as the sum of all individual item scores. Each of the 10 symptoms of depression on MADRS is measured on a scale of 0 to 6 with 0 representing the lowest severity of the symptom and 6 representing the highest severity.
Time Frame	1 year

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.
The intent-to-treat (ITT) population consisted of all subjects who have taken any open-label study medication.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Change in Total Score From Baseline in Montgomery-Asberg Depression Rating Scale (MADRS). [Units: Units on a scale] Mean (Standard Deviation)	**-1.5 (6.17)**

No statistical analysis provided for Change in Total Score From Baseline in Montgomery-Asberg Depression Rating Scale (MADRS).

16. Secondary: Change in Total Score From Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) in Those Subjects With a MADRS Score of ≥14 at Screening [Time Frame: baseline and Month 12]

Measure Type	Secondary
Measure Title	Change in Total Score From Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) in Those Subjects With a MADRS Score of ≥14 at Screening
Measure Description	The total score of MADRS is defined as the sum of all individual item scores . Each of the 10 symptoms of depression on MADRS is measured on a scale of 0 to 6 with 0 representing the lowest severity of the symptom and 6 representing the highest severity.
Time Frame	baseline and Month 12

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.
The intent-to-treat (ITT) population consisted of all subjects who have taken any open-label study medication.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**274**
Change in Total Score From Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) in Those Subjects With a MADRS Score of ≥14 at Screening [Units: Units on a scale] Mean (Standard Deviation)	**-1.5 (6.17)**

No statistical analysis provided for Change in Total Score From Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) in Those Subjects With a MADRS Score of ≥14 at Screening

17. Secondary: Completion Rate (% of Subjects Completing Each Visit Post-one Year). [Time Frame: post 1 year]

Measure Type	Secondary
Measure Title	Completion Rate (% of Subjects Completing Each Visit Post-one Year).
Measure Description	Completion rate (% of subjects completing each visit post-one year).
Time Frame	post 1 year

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.
The intent-to-treat (ITT) subjects who entered the post - 1- year open -label period.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Measured Values

	Eslicarbazepine Acetate
Participants Analyzed	**198**
Completion Rate (% of Subjects Completing Each Visit Post-one Year). [Units: Percentagae of participants]	**66.7**

No statistical analysis provided for Completion Rate (% of Subjects Completing Each Visit Post-one Year).

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	1 year
Additional Description	No text entered.

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Serious Adverse Events

	Eslicarbazepine Acetate
Total, All-Cause Mortality	
# participants affected / at risk	**2/274 (0.73%)**
Total, Serious Adverse Events	

# participants affected / at risk	**32/274 (11.68%)**
Cardiac disorders	
sinus tachycardia † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
Ear and labyrinth disorders	
vertigo † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
Gastrointestinal disorders	
abdominal pain upper † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
colitis † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
pancreatitis † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
vomiting † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
General disorders	
non-cardiac chest pain † 1	
# participants affected / at risk	**3/274 (1.09%)**
# events	**3**
irritability † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
sudden unexplained death in epilepsy † 1	
# participants affected / at risk	**1/274 (0.36%)**

# events	1
Hepatobiliary disorders	
cholelithiasis obstructive † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
Infections and infestations	
chronic sinusitis † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
histoplasmosis † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
pneumonia † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
tooth infection † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
Injury, poisoning and procedural complications	
accidental overdose † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
collapse of lung † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
fall † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
post concussion syndrome † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
Therapeutic agent toxicity † 1	
# participants affected / at risk	1/274 (0.36%)

# events	**1**
Investigations	
electroencephalogram † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
Metabolism and nutrition disorders	
failure to thrive † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
Musculoskeletal and connective tissue disorders	
arthritis † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
muscle twitching † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
Osteoarthritis † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
fallopian tube cancer † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
non-small cel lung cancer metastatic † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
ovarian cancer † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
Nervous system disorders	
partial seizures with secondary generalisation † 1	

# participants affected / at risk	7/274 (2.55%)
# events	7
complex partial seizures † 1	
# participants affected / at risk	3/274 (1.09%)
# events	3
simple partial seizures † 1	
# participants affected / at risk	2/274 (0.73%)
# events	2
akathisia † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
grand mal convulsion † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
postictal paralysis † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
status epilepticus † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
Psychiatric disorders	
depression † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
suicidal ideation † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
Renal and urinary disorders	
nephrolithiasis † 1	
# participants affected / at risk	1/274 (0.36%)
# events	1
Respiratory, thoracic and mediastinal disorders	
emphysema † 1	

# participants affected / at risk	**1/274 (0.36%)**
# events	**1**
Vascular disorders	
accelerated hypertension † 1	
# participants affected / at risk	**1/274 (0.36%)**
# events	**1**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA (13.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	1 year
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Eslicarbazepine Acetate	Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Other Adverse Events

	Eslicarbazepine Acetate
Total, Other (not including serious) Adverse Events	
# participants affected / at risk	**166/274 (60.58%)**
Gastrointestinal disorders	

nausea † 1	
# participants affected / at risk	**24/274 (8.76%)**
# events	**31**
vomiting † 1	
# participants affected / at risk	**16/274 (5.84%)**
# events	**20**
diarrhoea † 1	
# participants affected / at risk	**15/274 (5.47%)**
# events	**19**
General disorders	
fatigue † 1	
# participants affected / at risk	**23/274 (8.39%)**
# events	**25**
Infections and infestations	
nasopharyngitis † 1	
# participants affected / at risk	**24/274 (8.76%)**
# events	**35**
influenza † 1	
# participants affected / at risk	**14/274 (5.11%)**
# events	**15**
Injury, poisoning and procedural complications	
fall † 1	
# participants affected / at risk	**20/274 (7.30%)**
# events	**33**
Musculoskeletal and connective tissue disorders	
back pain † 1	
# participants affected / at risk	**16/274 (5.84%)**
# events	**16**
Nervous system disorders	
headache † 1	
# participants affected / at risk	**64/274 (23.36%)**
# events	**144**

dizziness † 1	
# participants affected / at risk	**46/274 (16.79%)**
# events	**81**
complex partial seizures † 1	
# participants affected / at risk	**14/274 (5.11%)**
# events	**18**
Psychiatric disorders	
depression † 1	
# participants affected / at risk	**18/274 (6.57%)**
# events	**19**
insomnia † 1	
# participants affected / at risk	**15/274 (5.47%)**
# events	**18**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA (13.1)

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** 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.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** In the event the Study is part of a multi-center study, the first publication of the results of the Study shall be made in conjunction with the results of other participating study sites as a multi-center publication; provided however, if a multi-center publication is not forthcoming within twenty-four (24) months following completion of the Study at all sites, Institution and Investigator shall be free to publish.

Results Point of Contact:

Name/Title: CNS Medical Director
Organization: Sunovion Pharmaceuticals Inc.
phone: 1-866-503-6351
e-mail: clinicaltrialsdisclosure@sunovion.com

Responsible Party:	Sunovion
ClinicalTrials.gov Identifier:	NCT00910247 History of Changes
Other Study ID Numbers:	**093-050**
First Submitted:	May 27, 2009
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