Evaluating E2007 (Perampanel) in Patients With Painful Diabetic Neuropathy (PDN) or Post-Herpetic Neuralgia (PHN)

This study has been completed.

Sponsor:
Eisai Inc.

Information provided by (Responsible Party):
Eisai Inc.

ClinicalTrials.gov Identifier:
NCT00592904

First received: January 3, 2008
Last updated: December 17, 2015
Last verified: November 2015
History of Changes

Purpose

The purpose of this study is to evaluate the safety, tolerability and continued efficacy of perampanel in patients previously enrolled in double-blind, placebo-controlled studies for Painful Diabetic Neuropathy (PDN) or Post-Herpetic Neuralgia (PHN).

Condition	Intervention	Phase
Neuralgia	Drug: E2007	Phase 2 Phase 3

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Multi-Center, Open-Label Extension Study to Evaluate the Long-Term Safety, Tolerability, and Efficacy of E2007 (Perampanel) in Patients With Painful Diabetic Neuropathy (PDN) or Post-Herpetic Neuralgia (PHN)

Resource links provided by NLM:

MedlinePlus related topics: Diabetic Nerve Problems Shingles

Drug Information available for: Perampanel

U.S. FDA Resources

Further study details as provided by Eisai Inc.:

Primary Outcome Measures:

- Mean Change From Baseline in Short Form-McGill Pain Questionnaire (SF-MPQ): Sensory and Affective Scores, From Baseline to Week 48. [Time Frame: Baseline and Week 48] [Designated as safety issue: No]

  Mean change from baseline to open-label study endpoint and other study visits in SF-MPQ scores sensory and affective). SF-MPQ was

completed to assess intensity of pain over the past 48 days for all 15 descriptors: throbbing, shooting, stabbing, sharp, cramping, gnawing, hot-burning, aching, heavy, tender, splitting,tiring-exhausting, sickening, fear-causing, punishing-cruel. Each descriptor was scored by participant on a 4-point intensity scale (0=none to 3=severe) and totaled in each subclass (sensory range 0-45); higher scores indicated higher intensity of pain.

- Mean Change From Baseline in SF-MPQ Visual Analog Scale (VAS): From Baseline to Week 48. [Time Frame: Baseline and Week 48] [Designated as safety issue: No]

  SF-MPQ VAS consists of a line 0 to 100 millimeters (mm) in length; range is 0 (no pain) to 100 mm (worst possible pain). Subjects placed a mark indicating the intensity of their pain. Distance from left-hand end of line was measured and entered on Case Report Form (CRF) as score in mm. Higher score indicates greater level of pain.

- Mean Change From Baseline in SF-MPQ Current Pain Intensity (CPI): From Baseline to Week 48 [Time Frame: Baseline and Week 48] [Designated as safety issue: No]

  Mean change from baseline in SF-MPQ (CPI) at study endpoint. Affective score ranges from 0-5. Higher scores indicate more severe pain (0=no pain, 1=mild, 2=discomforting, 3=distressing, 4=horrible, 5=excrutiating).

Secondary Outcome Measures:

- Analysis of Patient Global Impression of Change (PGIC) at Week 48/End of Treatment (EOT) [Time Frame: Baseline and Week 48] [Designated as safety issue: No]

  The PGIC asked subjects to evaluate the change in their overall status compared with the start of open-label treatment on a scale ranging from 1 (very much improved) to 7 (very much worse). [Please note high withdrawl rate during study].

- Mean Change From Baseline in Short Form 36 Item (SF-36) Health Survey: Physical and Mental Component Scores From Baseline to Week 48/EOT [Time Frame: Baseline and Week 48] [Designated as safety issue: No]

  Mean change from baseline in SF-36 Item Health Survey Scores at study endpoint. Each component on the SF-36 Item Health Survey is scored from 0-100 with higher scores reflecting better subject status.

Enrollment:	262
Study Start Date:	January 2008
Study Completion Date:	July 2011
Primary Completion Date:	November 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1	Drug: E2007 Perampanel doses will be up-titrated in 2 mg steps at minimum weekly intervals starting at 2 mg daily and up-titrated to 12 mg daily (taken orally). Other Name: Perampanel

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

Each patient must meet all of the following criteria to be enrolled in this study:

1. Met and continues to meet all inclusion and none of the exclusion criteria for the preceding PDN or PHN study and received study drug or placebo under double-blind conditions.
2. Completed the preceding double-blind study End of Treatment (EOT) Visit no more than 12 weeks prior to Baseline (Visit 1) for the open-label study. The eligibility status of patients who do not enroll during this 12 week period will be evaluated on a case by case basis via discussion between the Investigator and the Sponsor.

3. Males and females ≥18 years of age. Female patients should be either of nonchildbearing potential as a result of surgery or menopause (1 year after onset), or of childbearing potential and practicing a medically acceptable method of contraception (e.g., abstinence, a barrier method plus spermicide, or intrauterine device [IUD]) for at least 1 month before the Baseline Visit (Visit 1) and for 1 month after the end of the study (Visit 16). They must also have a negative pregnancy test at Baseline (Visit 1). Female patients using hormonal contraceptives must also be using an additional approved method of contraception (e.g., a barrier method plus spermicide or IUD) throughout the study.
4. Provide written informed consent prior to entering the study and prior to undergoing any study-related procedures.
5. Is reliable, willing, and able to cooperate with the study procedures.

Exclusion Criteria:

Patients who meet the following criterion will be excluded from this study:

1. Patients who discontinued early for any reason from the preceding double-blind study.
2. Patients who have a clinically significant finding(s) that would make them unsuitable for the study in the opinion of the investigator or Sponsor.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00592904

Locations

United States, Illinois

Chicago, Illinois, United States, 60610

Sponsors and Collaborators

Eisai Inc.

Investigators

Study Director: Antonio Laurenza, M. D. Eisai Inc.

More Information

Responsible Party:	Eisai Inc.
ClinicalTrials.gov Identifier:	NCT00592904 History of Changes
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Results First Received:	October 23, 2012
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Health Authority:	United States: Food and Drug Administration European Union: European Medicines Agency

Keywords provided by Eisai Inc.:
Neuralgia
neuropathy

Additional relevant MeSH terms:

Neuralgia	Peripheral Nervous System Diseases
Diabetic Neuropathies	Neuromuscular Diseases
Neuralgia, Postherpetic	Signs and Symptoms
Pain	Diabetes Complications
Neurologic Manifestations	Diabetes Mellitus
Nervous System Diseases	Endocrine System Diseases

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