

EISAI TO PRESENT LATEST DATA ON PERAMPANEL AT THE 76TH AMERICAN EPILEPSY SOCIETY (AES) ANNUAL MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the company will have a total of 34 poster presentations, including the latest data on its in-house discovered and developed anti-epileptic agent (AED) perampanel (product name: Fycompa®) at the 76th American Epilepsy Society Annual Meeting (AES 2022), to be held in Nashville, Tennessee and virtually from December 2-6, 2022.

Key data Presentations for perampanel include the:

- Results from a post hoc analysis of the phase III clinical trial (FREEDOM/342), which evaluated long-term efficacy of perampanel monotherapy by seizure type in the open-label extension (52 weeks) for epilepsy patients with focal-onset seizures (FOS), ≥ 12 years of age without prior treatment history (poster number: 2.228)
- Real-world pooled analyses of perampanel for pediatric patients (poster number: 1.310), adolescent patients (poster number: 1.313) and elderly patients (poster number: 1.312)
- Results from a post hoc analysis of two phase III open-label extension (OLEx) studies, Study 307 and Study 335 OLEx, evaluating the long-term efficacy and safety of adjunctive perampanel in a subgroup of older adult patients aged ≥ 60 years (poster number: 1.291)

"With 34 poster presentations planned for this year's AES Meeting, we look forward to furthering our understanding of the results that may impact overall care in epilepsy," said Ivan Cheung, Senior Vice President Global Alzheimer's Disease Officer President, Americas Region, Eisai Co., Ltd., "We remain focused on addressing the diverse needs of patients with epilepsy and their families."

Perampanel is a first-in-class AED discovered by Eisai's Tsukuba Research Laboratories. The agent is a highly selective, noncompetitive AMPA receptor antagonist that is postulated to reduce neuronal hyper-excitation associated with seizures by targeting glutamate activity at AMPA receptors on postsynaptic membranes. The agent is currently approved for partial-onset seizures (with or without secondarily generalized seizures) in over 70 countries including Japan, the United States, China and other countries in Europe and in Asia. The agent is currently approved as an adjunctive therapy for primary generalized tonic-clonic seizures in over 70 countries including Japan, the United States, and other countries in Europe and in Asia.

Eisai considers neurology, including epilepsy, a therapeutic area of focus. Eisai pursues its mission to provide "seizure freedom" to a greater number of patients with epilepsy. Eisai remains committed further to addressing the diverse needs of, and increasing the benefits provided to, patients with epilepsy and their families.

The following are studies that will be presented by Eisai at this year's AES Annual Meeting.

Main poster presentations

Compound Poster Number Planned Date and Time (Central Standard Time)	Abstract Title
Perampanel Poster Number: 1.291 Poster presentation: Saturday, December 3 Poster Discussion: 12:00 – 2:00 p.m.	Long-Term Efficacy and Safety of Perampanel in a Subgroup of Older Adult Patients Aged ≥ 60 Years from Phase III Open-Label Extension (OLEx) Studies
Perampanel Poster Number: 1.310 Poster presentation: Saturday, December 3 Poster Discussion: 12:00 – 2:00 p.m.	Real-World Experience of Treating Patients Aged <12 Years with Perampanel
Perampanel Poster Number: 1.312 Poster presentation: Saturday, December 3 Poster Discussion: 12:00 – 2:00 p.m.	Perampanel for Treatment of Focal and Generalized Epilepsy in Elderly Patients (Aged ≥ 65 years) in Clinical Practice: Evidence from PERMIT and PROVE
Perampanel Poster Number: 1.313 Poster presentation: Saturday, December 3 Poster Discussion: 12:00 – 2:00 p.m.	Perampanel for Treatment of Adolescent Patients (Aged 12 to <18 years): Real-World Evidence from PERMIT and PROVE
Perampanel Poster Number: 2.121 Poster presentation: Sunday, December 4 Poster Discussion: 12:00 – 2:00 p.m.	Efficacy and Safety of Perampanel as First or Only Adjunctive Therapy in Patients with Focal-Onset Seizures (FOS) or Generalized Tonic-Clonic Seizures (GTCS) in Studies 412, 501, 410, and 509
Perampanel Poster Number: 2.124 Poster presentation: Sunday, December 4 Poster Discussion: 12:00 – 2:00 p.m.	A Mirroring Clinical Practice Study of Perampanel in Adults and Adolescents (AMPA): Assessment of Impact of Perampanel on Seizure Control, Sleep, and Quality of Life (QoL)
Perampanel Poster Number: 2.129 Poster presentation: Sunday, December 4 Poster Discussion: 12:00 – 2:00 p.m.	PERPRISE Study (PERampanel in patients with PRImary or SEcondarily generalized seizures): First Interim Analysis
Perampanel Poster Number: 2.220 Poster presentation: Sunday, December 4 Poster Discussion: 12:00 – 2:00 p.m.	Perampanel in Older Adult Patients Receiving Perampanel as First or Second Adjunctive therapy: An Overview of Data from Studies 412 and 501
Perampanel Poster Number: 2.228 Poster presentation: Sunday, December 4 Poster Discussion: 12:00 – 2:00 p.m.	Long-Term Efficacy of Perampanel Monotherapy in Patients with Newly Diagnosed/Currently Untreated Recurrent Focal-Onset Seizures: FREEDOM Study 342 Extension Phase Analysis by Seizure Type
Perampanel Poster Number: 2.229 Poster presentation: Sunday, December 4 Poster Discussion: 12:00 – 2:00 p.m.	ELEVATE Study 410: Analysis of Time to First Seizure with Perampanel as Monotherapy or First Adjunctive Therapy in Patients with Focal-Onset Seizures (FOS) or Generalized Tonic-Clonic Seizures (GTCS)

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

U.S. Media Inquiries:
Christopher Vancheri
Eisai Inc.
551-305-0050
Christopher_vancheri@eisai.com

[Notes to Editors]

1. About perampanel (product name: Fycompa)

Perampanel is a first-in-class anti-epileptic agent (AED) discovered and developed by Eisai. With epileptic seizures being mediated by the neurotransmitter glutamate, the agent is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at AMPA receptors on postsynaptic membranes. Perampanel is currently approved in more than 70 countries and territories, including Japan, the United States, China, and other countries in Europe and in Asia as an adjunctive treatment for partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy 12 years of age and older. In addition, perampanel has been approved in more than 70 countries, including the United States, Japan, in Europe and in Asia for treatment as an adjunctive therapy for primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. In Japan, the United States and China, perampanel is approved for monotherapy and adjunctive use in the treatment of partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy 4 years of age and older. In Europe the approved age range is 4 years of age and older for the adjunctive treatment of partial-onset seizures (with or without secondarily generalized seizures) and 7 years of age and older for the treatment as an adjunctive therapy for primary generalized tonic-clonic seizure. perampanel is available in drug form to be taken once daily orally at bedtime. A tablet and fine granule formulation have been approved in Japan. An oral suspension formulation and tablet have been approved in the United States and Europe. A supplementary new drug application for an injection formulation has been submitted in Japan as a new route of administration. To date, perampanel has been used to treat more than 500,000 patients worldwide across all indications.

2. About Epilepsy

Epilepsy is broadly categorized by seizure type, with partial-onset seizures accounting for approximately 60% of epilepsy cases and generalized seizures accounting for approximately 40%. In a partial-onset seizure, an abnormal electrical disturbance occurs in a limited area of the brain, and may subsequently spread throughout the brain, becoming a generalized seizure (known as a secondarily generalized seizure). In a generalized seizure, abnormal electrical disturbances occur throughout the brain, and can be followed by a loss of consciousness or physical symptoms manifested throughout the whole body.

Epilepsy affects approximately 3.4 million people in the United States, 1 million people in Japan, 6 million people in Europe, 9 million people in China, and approximately 60 million people worldwide. As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs,^{*} this is a disease with significant unmet medical needs. Although onset occurs at any age, onset is most common in people aged 18 and younger and the elderly. As causes and clinical symptoms of pediatric epilepsy are not uniform, and prognoses can range from very positive cases to obstinate cases, special consideration for each patient is required of treatments.

^{*}“The Epilepsies and Seizures: Hope Through Research. What are the epilepsies?” National Institute of Neurological Disorders and Stroke, accessed May 24, 2016,
http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#230253109