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Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA ON PERAMPANEL AT THE 74TH AMERICAN EPILEPSY SOCIETY ANNUAL MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that the company will present the latest data on its in-house discovered and developed anti-epileptic agent (AED) perampanel (product name: Fycompa®), at the 74th American Epilepsy Society Annual Meeting (AES2020), to be held virtually from December 4 to 8, 2020.

A total of 43 poster presentations regarding perampanel are planned, including analysis results from the phase III clinical trial (FREEDOM/Study 342), which evaluated the effectiveness and safety of the perampanel monotherapy in the open-label extension (52 weeks) for epilepsy patients with partial onset seizures (POS) from 12 to 74 years of age without prior treatment history. Additionally, results from the phase III clinical trial Study 311 evaluating safety and tolerability of perampanel as an adjunctive therapy in pediatric epilepsy patients with POS or primary generalized tonic clonic (PGTC) seizures from 4 to less than 12 years of age will be presented.

Perampanel is a first-in-class AED discovered at 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. In Japan and the United States, perampanel is currently approved for monotherapy and adjunctive use in the treatment of POS (with or without secondarily generalized seizures) in patients with epilepsy 4 years of age and older, as well as adjunctive treatment for primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older.

Eisai considers neurology, including epilepsy, a therapeutic area of focus. As we provide perampanel globally, Eisai pursues its mission to provide “seizure freedom” to a greater number of patients with epilepsy. Eisai seeks to address the diverse needs of, as well as increase the benefits provided to, patients with epilepsy and their families.

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■ Main poster presentations*

Poster Number	Abstract title/Planned Date and Time (Eastern Standard Time)
299 Poster session 2	Perampanel for the Treatment of Focal and Generalized Seizures in Patients with Epilepsy with Tumor Etiology: Evidence from Clinical Practice Live poster discussion: December 6 (Sun.) 12:00 - 13:30
347 Poster session 2	Long-Term (52 weeks) Effects of Adjunctive Perampanel on Cognition, Growth, and Development in Japanese Pediatric Patients (Aged 4 to <12 Years) with Partial-Onset Seizures in Study 311 Live poster discussion: December 6 (Sun.) 12:00 - 13:30
358 Poster session 2	Exploring the Evidence for Broad-Spectrum Effectiveness of Perampanel: Rationale and Methods of a Systematic Review of Clinical Data in Generalized Seizures Live poster discussion: December 6 (Sun.) 12:00 - 13:30
555 Poster session 3	Clinical Factors Associated with Seizure Freedom in Patients with Partial-Onset Seizures (POS) Receiving Perampanel 4 mg/day in FREEDOM Study 342 Live poster discussion: December 6 (Sun.) 17:15 - 18:45
556 Poster session 3	Sustained Seizure Freedom with Perampanel 4 mg/day Monotherapy in Patients with Newly Diagnosed/Currently Untreated Recurrent Partial-Onset Seizures: Post Hoc Analysis of Study 342 (FREEDOM) Live poster discussion: December 6 (Sun.) 17:15 - 18:45
567 Poster session 3	Open-label Phase 2 Study to Evaluate the Interchangeability of the Novel Intravenous Formulation of Perampanel from Oral Tablet in Japanese Patients with Epilepsy Live poster discussion: December 6 (Sun.) 17:15 - 18:45
762 Poster session 4	Long-term Evaluation of Adjunctive Perampanel on Mental Health in Pediatric Patients with Partial-Onset Seizures (POS) or Primary Generalized Tonic-Clonic Seizures (PGTCS) in Study 311 Live poster discussion: December 7 (Mon.) 9:00 - 10:30
979 Poster session 4	Perampanel Plasma Concentrations and Clinical Effects Following 4 mg/day Monotherapy in Patients with Partial-Onset Seizures (POS): Post Hoc Analysis of Study 342 (FREEDOM) Live poster discussion: December 7 (Mon.) 9:00 - 10:30

*Note: Posters will be available from December 4 on the conference website and remain available for 90 days.

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[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 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.

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 Europe the approved age range has been expanded to 4 years and above. In addition, perampanel has been approved in more than 65 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 Europe the approved age range has been expanded to 7 years and above. In Japan and the United States, 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.

To date, perampanel has been used to treat more than 300,000 patients worldwide across all indications.

Eisai is conducting a global Phase III clinical study (Study 338) for the agent in patients with seizures associated with Lennox-Gastaut syndrome. In addition, Eisai is conducting development of an injection formulation.

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 1 million people in Japan, 3.4 million people in the United States, 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