No.21-94

November 30, 2021
Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA ON PERAMPANEL AND E2730 AT THE 75TH AMERICAN EPILEPSY SOCIETY ANNUAL MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that the company will conduct a total of 42 poster presentations, including the latest data on its in-house discovered and developed anti-epileptic agent (AED) perampanel (product name: Fycompa®) and in-house discovered and developed E2730, an investigational novel small compound for AED and the treatment for neurological diseases, at the 75th American Epilepsy Society Annual Meeting (AES2021), to be held in Chicago, Illinois and virtually from December 3 to 7, 2021.

Major presentations regarding perampanel include poster presentations about the analysis results from the phase III clinical trial (FREEDOM/Study 342), which evaluated long-term efficacy and safety of the perampanel monotherapy in the open-label extension (52 weeks) for epilepsy patients with focal-onset seizures (FOS) from 12 to 74 years of age without prior treatment history (Poster number: 1.283). Additionally, an overview of phase III and other clinical studies (Poster number: 2.218) and a real-world pooled analysis of perampanel for elderly patients (Poster number: 1.215), will be presented. For E2730, a poster presentation will be given on the non-clinical study results (Poster number 2.197).

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 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.
E2730 is a novel selective uncompetitive GAT-1 (GABA transporter-1) inhibitor with a novel mechanism of action that selectively regulates activated synaptic functions, which was discovered by Eisai's Tsukuba Research Laboratories. Clinical study of E2730 for epilepsy is underway.

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.

(continued on following page)

■ Main poster presentations

Compound Poster Number Planned Date and Time (Central Standard Time)	Abstract Title
Perampanel Poster No: 1.215 Poster presentation: December 4 (Sat) Poster discussion:12:00-14:00	The Use of Perampanel in Elderly Epilepsy Patients: Pooled Analysis of Real-World Studies
E2730 Poster No: 2.197 Poster presentation: December 5 (Sun) Poster discussion:12:00-14:00	Discovery of E2730, A Novel Selective Uncompetitive GAT-1 Inhibitor: In Vivo Characteristics
Perampanel Poster No: 2.201 Poster presentation: December 5 (Sun) Poster discussion:12:00-14:00	Long-Term Perampanel Monotherapy and Health-Related Quality of Life in Patients with Newly Diagnosed/Currently Untreated Recurrent Focal-Onset Seizures (FOS): FREEDOM Study 342 Extension Phase
Perampanel Poster No: 2.218 Poster presentation: December 5 (Sun) Poster discussion:12:00-14:00	Perampanel in Elderly Patients: An Overview of Data from Studies 307, 335, 412, 342, and 506
Perampanel Poster No: 3.219 Poster presentation: December 6 (Mon) Poster discussion:12:00-13:45	Perampanel for the Treatment of Pediatric Patients in Clinical Practice by Age Category
Perampanel Poster No: 1.283 Virtual	Long-Term Efficacy and Safety of Perampanel Monotherapy in Patients with Newly Diagnosed/Currently Untreated Recurrent Focal-Onset Seizures (FOS): FREEDOM Study 342 Extension Phase
Perampanel Poster No: 2.202 Virtual	Long-Term Seizure Freedom with Adjunctive Perampanel in Patients with Focal-Onset and Focal to Bilateral Tonic-Clonic Seizures: Post Hoc Analysis of Study 335 Open-Label Extension (OLEx)
Perampanel Poster No: 2.208 Virtual	Assessment of Cognition (EpiTrack®) and Depression (Beck Depression Inventory-II) Following Perampanel (Monotherapy/First Adjunctive) in Patients with Epilepsy Enrolled in the ELEVATE Phase IV Study

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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 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 has been expanded to 4 years and above.

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 Europe the approved age range has been expanded to 7 years and above.

To date, perampanel has been used to treat more than 410,000 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 E2730

E2730 is a novel selective uncompetitive GAT-1 (GABA transporter-1) inhibitor with a novel mechanism of action that selectively regulates activated synaptic functions, which was discovered by Eisai's Tsukuba Research Laboratories. Clinical study for epilepsy is underway.

3. 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