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Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA ON LEMBOREXANT AND PERAMPANEL AT ANNUAL AMERICAN ACADEMY OF NEUROLOGY MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the latest data on its dual orexin receptor antagonist lemborexant and its antiepileptic drug (AED) perampanel (product name: Fycompa®) will be presented at the 2019 Annual American Academy of Neurology (AAN) Meeting to be held from May 4 to 10, 2019 in Philadelphia, Pennsylvania in the United States.

As major presentations, an oral presentation will be given on the next-morning residual effects of lemborexant from the results of three placebo-controlled, active comparator, randomized, double-blind clinical studies evaluating on-road driving performance as well as postural stability, and memory and attention performance directly after awakening.
Regarding perampanel, a total of 18 poster presentations will be given, including on the final analysis results from a Phase III clinical study (Study 311) in pediatric patients aged 4 to 12 years old with epilepsy, as well as on inpatient hospitalization risk in patients with epilepsy before and after perampanel treatment.

Eisai considers neurology a therapeutic area of focus, and strives to maximize the value of lemborexant and perampanel to further contribute to addressing the diverse needs of, as well as increasing the benefits provided to, patients and their families.

Oral presentations:

Presentation number and scheduled presentation date (local time)	**Abstract title**
Session 46：Sleep Science and Therapy Updates *Thursday May 9* *Poster presentation: 13:00-15:00*	Effects of lemborexant in the morning: results from 3 randomized studies

Poster presentations:

Poster number and scheduled presentation date (local time)	**Abstract title**
Poster number: 5-009 *Poster session: P1* *Sunday May 5* *Poster presentation: 17:30-18:30*	Symptoms and Impacts in Epilepsy: Findings from Qualitative Patient Interviews

(continued on following page)

Poster number and scheduled presentation date (local time)	Abstract title
Poster number: 5-021 *Poster session: P1* *Sunday May 5* *Poster presentation: 17:30-18:30*	Safety and efficacy of adjunctive perampanel in younger (aged 4 to <7 years) and older (7 to <12 years) pediatric patients with partial-onset seizures (POS) or primary generalized tonic-clonic seizures (PGTCS) : Final Results from the 311 Core Study
Poster number: 5-024 *Poster session: P1* *Sunday May 5* *Poster presentation: 17:30-18:30*	A Post-Marketing Observational Study to Evaluate the Safety and Tolerability of Perampanel as Add-On Therapy in Patients with Epilepsy Aged ≥12 Years
Poster number: 5-029 *Poster session: P1* *Sunday May 5* *Poster presentation: 17:30-18:30*	Pharmacokinetic (PK) Assessment of Perampanel Intravenous (IV) Formulation as a Bioequivalent Alternative to Oral Tablet Administration
Poster number: 5-001 *Poster session: P3* *Tuesday May 7* *Poster presentation: 17:30-18:30*	Safety and Efficacy of Adjunctive Perampanel in Pediatric Patients (Aged 4 to <12 Years) with Partial-Onset Seizures (POS) or Primary Generalized Tonic-Clonic Seizures (PGTCS): Final Results from the 311 Core Study
Poster number: 5-002 *Poster session: P3* *Tuesday May 7* *Poster presentation: 17:30-18:30*	Risk of Hospitalization in Patients With Uncontrolled Epilepsy Treated with a Long Versus Short Half-Life Adjunctive Antiepileptic Medication
Poster number: 5-005 *Poster session: P3* *Tuesday May 7* *Poster presentation: 17:30-18:30*	Perampanel Use in Established, Refractory, and Super-Refractory Status Epilepticus (SE): a Summary of Cases from Austria, Finland, Germany, and Spain
Poster number: 5-007 *Poster session: P3* *Tuesday May 7* *Poster presentation: 17:30-18:30*	Effect of Concomitant Enzyme-Inducing Antiepileptic Drugs (EIAEDs) on the Safety and Efficacy of Adjunctive Perampanel in Patients Aged 4 to <12 years with Partial-Onset Seizures (POS): Final Results from the 311 Core Study
Poster number: 5-017 *Poster session: P3* *Tuesday May 7* *Poster presentation: 17:30-18:30*	Phase II, Open-Label Pharmacokinetic (PK) Study of Perampanel Oral Suspension as Adjunctive Therapy in Pediatric Patients (Aged ≥1 to <24 months) with Epilepsy: Study 238 Design and Preliminary Safety Data
Poster number: 5-018 *Poster session: P3* *Tuesday May 7* *Poster presentation: 17:30-18:30*	Inpatient Hospitalizations Rates in Patients Diagnosed with Epilepsy and Treated with Perampanel or Lacosamide
Poster number: 5-019 *Poster session: P3* *Tuesday May 7* *Poster presentation: 17:30-18:30*	Study 410 Enrollment Update: Multicenter, Open-label, Phase IV Study of Perampanel as Monotherapy or First Adjunctive Therapy in Patients with Partial-Onset Seizures (POS) or Primary Generalized Tonic-Clonic Seizures (PGTCS)
Poster number: 5-022 *Poster session: P3* *Tuesday May 7* *Poster presentation: 17:30-18:30*	Inpatient Hospitalization Risk in Patients with Epilepsy Before and After Perampanel Treatment
Poster number: 5-027 *Poster session: P3* *Tuesday May 7* *Poster presentation: 17:30-18:30*	Elevated Healthcare Burden Amongst Patients with Active Generalized Tonic-Clonic (GTC) Convulsions

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Poster number and scheduled presentation date (local time)	Abstract title
Poster number: 5-004 *Poster session: P5* *Thursday May 9* *Poster presentation: 17:30-18:30*	Adjunctive Perampanel in Pediatric Patients with Epilepsy: Population Pharmacokinetic (PK) and Exposure-response Analyses
Poster number: 5-008 *Poster session: P5* *Thursday May 9* *Poster presentation: 17:30-18:30*	Perampanel in Real-World Clinical Care of Patients with Epilepsy: Retrospective Phase IV Study 506 – Second Interim Analysis
Poster number: 5-009 *Poster session: P5* *Thursday May 9* *Poster presentation: 17:30-18:30*	Study 506 – Second Interim Analysis of a Retrospective, Phase IV Study of Perampanel in Real-World Clinical Care of Patients with Epilepsy: Pediatric Subgroup (Aged <12 Years)
Poster number: 5-014 *Poster session: P5* *Thursday May 9* *Poster presentation: 17:30-18:30*	Inpatient Hospitalization Risk in Medicaid Patients with Epilepsy Before and After Perampanel Treatment
Poster number: 5-017 *Poster session: P5* *Thursday May 9* *Poster presentation: 17:30-18:30*	Study 506 – Second Interim Analysis of a Retrospective, Phase IV Study of Perampanel in Real-World Clinical Care of Patients with Epilepsy: Adolescent Subgroup (Aged 12 to <18 Years)

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<Notes to editors>

1. About Lemborexant

Lemborexant is a novel investigational small molecule compound, discovered and developed by Eisai in-house scientists, that inhibits orexin signaling by binding competitively to both orexin receptor subtypes (orexin receptor 1 and 2). In individuals with normal daily sleep-wake rhythms, orexin signaling is believed to promote periods of wakefulness. In individuals with sleep-wake disorders, it is possible that orexin signaling that regulates wakefulness is not functioning normally, suggesting that inhibiting inappropriate orexin signaling may enable initiation and maintenance of sleep. Additionally, a Phase 2 clinical study of lemborexant in patients with irregular sleep-wake rhythm disorder (ISWRD) and mild to moderate Alzheimer's dementia is underway.

2. About Perampanel (generic name, product name: Fycompa)

Perampanel is a first-in-class 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 tablet form to be taken once daily orally at bedtime. In addition, an oral suspension formulation has been approved in the United States.

Perampanel is currently approved in more than 55 countries and territories, including the United States, Japan, in Europe and in Asia as adjunctive treatment for partial-onset seizures (with or without secondarily generalized

seizures) in patients with epilepsy 12 years of age and older. An application seeking approval for use in the adjunctive treatment of partial-onset seizures is under review in China, which has been designated for Priority Review. In addition, Perampanel has been approved in more than 50 countries, including the United States, Japan, in Europe and in Asia for treatment as an adjunctive therapy for tonic-clonic seizures in patients with generalized epilepsy 12 years of age and older. In 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. In Japan, a supplementary new drug application has been filed seeking approval of Perampanel for use as monotherapy for partial-onset seizures, treatment for partial-onset seizures in pediatric patients aged 4 years and older, as well as a fine granule formulation. In Europe, an application has been submitted seeking the additional approval of Perampanel for adjunctive use in the treatment of partial-onset seizures (with or without secondarily generalized seizures) or primarily generalized tonic-clonic seizures in pediatric patients with epilepsy.

Furthermore, Eisai is conducting a global Phase III clinical study (Study 338) for the agent in patients with epileptic seizures associated with Lennox-Gastaut syndrome.