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Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA ON PERAMPANEL AT 73RD AMERICAN EPILEPSY SOCIETY ANNUAL MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the latest data on its antiepileptic drug (AED) perampanel (product name: Fycompa®) will be presented at the 73rd American Epilepsy Society Annual Meeting (AES 2019) to be held from December 6 to December 10, 2019 in Baltimore, Maryland in the United States.

Thirty-Eight poster presentations will be given by Eisai at AES 2019, including results of a Phase III clinical study (FREEDOM / Study 342) to assess efficacy and safety of perampanel monotherapy for untreated patients from 12 to 74 years of age with partial onset seizures and results of a retrospective Phase IV study (Study 506) of perampanel in real-world clinical care of patients with epilepsy. Including Investigator Initiated Studies, more than 40 scientific posters on perampanel will be presented at AES 2019.

Perampanel is a first-in-class AED and a once-daily tablet discovered at Eisai's Tsukuba Research Laboratories. In the United States and Europe, a new oral suspension formulation has been approved and is being marketed. The agent is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation by targeting glutamate activity at AMPA receptors on postsynaptic membranes. Perampanel is currently approved in countries around the world as an adjunctive therapy for the treatment of partial-onset seizures (with or without secondarily generalized seizures) and primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. Furthermore, perampanel is also indicated 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 the United States.

Eisai considers neurology including epilepsy, a therapeutic area of focus, and strives to deliver perampanel throughout the world in pursuit of our mission to provide "seizure freedom" to a greater number of patients living with epilepsy. Eisai seeks to address the diverse needs of, as well as increasing the benefits provided to, patients with epilepsy and their families.

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Major Poster Presentations for perampanel:

Abstract number **Date and time of presentation**	**Abstract title**
Study 342 (FREEDOM Study)	
Abstract number: #2.215 *Sunday December 8* *Poster presentation: 10:00-16:00* *Poster discussion: 12:00-14:00*	Efficacy and Safety of Perampanel Monotherapy in Patients with Newly Diagnosed or Currently Untreated Recurrent Partial-Onset Seizures: Final Analysis of Study 342 (FREEDOM) 4 and 8 mg/day Core Data
Abstract number: #3.318 *Monday December 9* *Poster presentation: 8:00-14:00* *Poster discussion: 12:00-14:00*	Perampanel Monotherapy in Patients (Pts) with Newly Diagnosed or Currently Untreated Recurrent Partial-Onset Seizures (POS): Efficacy and Safety in the Extension Phase of Study 342 (FREEDOM)
Study 506 (PROVE Study)	
Abstract number: #1.304 *Saturday December 7* *Poster presentation: 12:00-18:00* *Poster discussion: 12:00-14:00*	PROVE Study 506: Perampanel as Adjunctive Therapy or Monotherapy in Real-World Clinical Care of Patients with Epilepsy
Abstract number: #1.306 *Saturday December 7* *Poster presentation: 12:00-18:00* *Poster discussion: 12:00-14:00*	Perampanel in Real-World Clinical Care of Patients with Epilepsy at Duke University Medical Center, Durham, North Carolina: a Regional Comparison of Results from PROVE Study 506
Abstract number: #1.311 *Saturday December 7* *Poster presentation: 12:00-18:00* *Poster discussion: 12:00-14:00*	PROVE Study 506: Retrospective, Phase IV Study of Perampanel in Real-World Clinical Care of Patients Aged ≥18 Years with Epilepsy
Abstract number: #1.312 *Saturday December 7* *Poster presentation: 12:00-18:00* *Poster discussion: 12:00-14:00*	Perampanel in Real-World Clinical Care of Patients with Epilepsy: Results from the Retrospective, Phase IV PROVE Study 506
Abstract number: #1.313 *Saturday December 7* *Poster presentation: 12:00-18:00* *Poster discussion: 12:00-14:00*	PROVE Study 506: Retrospective, Phase IV Study of Perampanel in Real-World Clinical Care of Patients Aged <4 Years with Epilepsy
Abstract number: #2.209 *Sunday December 8* *Poster presentation: 10:00-16:00* *Poster discussion: 12:00-14:00*	PROVE Study 506: Retrospective, Phase IV Study of Perampanel in Real-World Clinical Care of Patients Aged 12 to <18 Years with Epilepsy
Abstract number: #3.301 *Monday December 9* *Poster presentation: 8:00-14:00* *Poster discussion: 12:00-14:00*	Perampanel in Real-World Clinical Care of Patients with Epilepsy: Effect of Enzyme-Inducing Anti-Seizure Drugs on Retention Rate in the Retrospective Phase IV PROVE Study 506
Abstract number: #3.303 *Monday December 9* *Poster presentation: 8:00-14:00* *Poster discussion: 12:00-14:00*	PROVE Study 506: Retrospective, Phase IV Study of Perampanel in Real-World Clinical Care of Patients Aged 4 to <12 Years with Epilepsy
Abstract number: #3.316 *Monday December 9* *Poster presentation: 8:00-14:00* *Poster discussion: 12:00-14:00*	Perampanel in Real-World Clinical Care of Patients with Epilepsy at Northeast Regional Epilepsy Group, Hackensack, New Jersey: a Regional Comparison of Results from PROVE Study 506

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Abstract number Date and time of presentation	Abstract title
Other major presentations	
Abstract number: #1.303 *Saturday December 7* *Poster presentation: 12:00-18:00* *Poster discussion: 12:00-14:00*	ELEVATE Study 410 Enrollment Update: Phase IV Study of Perampanel as Monotherapy or First Adjunctive Therapy in Patients Aged ≥12 Years with Partial-Onset or Primary Generalized Tonic-Clonic Seizures
Abstract number: #1.305 *Saturday December 7* *Poster presentation: 12:00-18:00* *Poster discussion: 12:00-14:00*	Efficacy and Safety of Perampanel as First Adjunctive Therapy in Patients with Partial-Onset Seizures: Post Hoc Analysis of the FAME Study by First-Line Antiepileptic Drug Use (Study 412)
Abstract number: #2.207 *Sunday December 8* *Poster presentation: 10:00-16:00* *Poster discussion: 12:00-14:00*	Perampanel Exposure–Response Relationships for Cognition and Safety in Pediatric Patients (Aged 4 to <12 years) with Epilepsy (study 311, 232)
Abstract number: #2.216 *Sunday December 8* *Poster presentation: 10:00-16:00* *Poster discussion: 12:00-14:00*	Adverse Event Profile with Perampanel as First Adjunctive Therapy in Patients with Partial-Onset Seizures: Analysis of the FAME Study (Study 412)

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

[Notes to editors]

1. About Fycompa (perampanel)

Fycompa 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. Fycompa is available in tablet form to be taken once daily orally at bedtime. In addition, an oral suspension formulation has been approved and marketed in the United States and in Europe. To date, Fycompa has been used to treat more than 270,000 patients worldwide across all indications.

Fycompa is currently approved in more than 65 countries and territories, including the United States, Japan, China, 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. In addition, Fycompa has been approved in more than 60 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 the United States, Fycompa is also indicated 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 Fycompa 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 Fycompa 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 seizures associated with Lennox-Gastaut syndrome.