No.19-42

June 14, 2019
Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA ON PERAMPANEL AT 33RD INTERNATIONAL EPILEPSY CONGRESS

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 33rd International Epilepsy Congress (IEC) to be held from June 22 to 26, 2019 in Bangkok, Thailand.

As major presentations, 2 oral presentations will be given including on the final analysis of a Phase III clinical study (Study 311) on adjunctive perampanel in pediatric patients aged 4 to less than 12 years old with epilepsy. Also, a total of 12 poster presentations will be given, including on the primary analysis from a Phase III clinical study (FREEDOM / Study 342), which was conducted in Japan and South Korea, on the efficacy and safety of perampanel monotherapy in untreated epilepsy patients with partial-onset seizures (with or without secondary generalized seizures).

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, an 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 secondary generalized seizures) and primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. Furthermore, in the United States, Perampanel is approved for monotherapy and adjunctive use in the treatment of partial-onset seizures (with or without secondary generalized seizures) in patients with epilepsy 4 years of age and older.

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.

Oral Presentations

Presentation Number and Scheduled Presentation Date (Local Time)	Abstract Title
Platform Session: Treatment *Oral Presentation:* *Monday, June 24th 15:30-15:45*	Safety and efficacy of adjunctive perampanel in paediatric patients (aged 4 to <12 years) with partial-onset seizures (POS) or primary generalised tonic-clonic seizures (PGTCS): final results from the 311 Core Study
Platform Session: Treatment *Oral Presentation:* *Monday, June 24th 15:45-16:00*	Effect of concomitant enzyme-inducing anti-seizure drugs (EIASDs) 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 Presentations

Presentation Number and Scheduled Presentation Date (Local Time)	Abstract Title
Poster # p125 *Poster Session: Drug Therapy 1* *Poster Presentation:* *Sunday, June 23rd 10:00-17:00*	First-line perampanel added to monotherapy in patients with partial-onset seizures, with or without secondary generalised seizures: A multicentre, open-label, prospective cohort study
Poster # p215 *Poster Session: Paediatric Epileptology 1* *Poster Presentation:* *Sunday, June 23rd 10:00-17:00*	Adjunctive perampanel in pediatric patients with epilepsy: population pharmacokinetic (PK) and exposure-response analyses
Poster # p317 *Poster Session: Drug Therapy 2* *Poster Presentation:* *Monday, June 24th 10:00-17:00*	Perampanel does not worsen myoclonic and absence seizures
Poster # p328 *Poster Session: Drug Therapy 2* *Poster Presentation:* *Monday, June 24th 10:00-17:00*	Perampanel in real-world clinical care of patients with epilepsy: retrospective Phase IV Study 506 (PROVE Study)
Poster # p329 *Poster Session: Drug Therapy 2* *Poster Presentation:* *Monday, June 24th 10:00-17:00*	Study 506 (PROVE Study) – a retrospective, Phase IV study of perampanel in real-world clinical care of patients with epilepsy: adolescent subgroup (aged 12 to <18 years)
Poster # p331 *Poster Session: Drug Therapy 2* *Poster Presentation:* *Monday, June 24th 10:00-17:00*	Efficacy and safety of adjunctive perampanel in Chinese patients with partial-onset seizures or primary generalised tonic-clonic seizures: post hoc analysis of Phase III double-blind and open-label extension studies
Poster # p410 *Poster Session:* *Paediatric Epileptology 2* *Poster Presentation:* *Monday, June 24th 10:00-17:00*	Safety and efficacy of adjunctive perampanel in younger (aged 4 to < 7 years) and older (7 to < 12 years) paediatric patients with partial-onset seizures (POS) or primary generalised tonic-clonic seizures (PGTCS): final results from the 311 Core Study

(continued on following page)

Presentation Number and Scheduled Presentation Date (Local Time)	Abstract Title
Poster # p413 *Poster Session:* *Paediatric Epileptology 2* *Poster Presentation:* *Monday, June 24th 10:00-17:00*	Study 506 (PROVE Study) – a retrospective, Phase IV study of perampanel in real-world clinical care of patients with epilepsy: paediatric subgroup (aged <12 years)
Poster # p424 *Poster Session:* *Paediatric Epileptology 2* *Poster Presentation:* *Monday, June 24th 10:00-17:00*	Effect of adjunctive perampanel on Clinical Global Impression (CGI) in paediatric patients (aged 4 to <12 years) with partial-onset seizures (POS) or primary generalised tonic-clonic seizures (PGTCS) in Study 311
Poster # p425 *Poster Session:* *Paediatric Epileptology 2* *Poster Presentation:* *Monday, June 24th 10:00-17:00*	Safety and efficacy of adjunctive perampanel in Japanese paediatric patients (aged 4 to < 12 years) with partial-onset seizures (POS) with or without secondarily generalised seizures (SGS): final results from the 311 Core Study
Poster # p315 *Poster Session: Drug Therapy 3* *Poster Presentation:* *Tuesday, June 25th 10:00-17:00*	Efficacy and safety of perampanel monotherapy in previously untreated patients with partial-onset seizures (POS): primary analysis of Study 342 (FREEDOM study)
Poster # p520 *Poster Session: Drug Therapy 3* *Poster Presentation:* *Tuesday, June 25th 10:00-17:00*	Efficacy and safety of adjunctive perampanel in Indian patients with partial-onset seizures (POS) or primary generalised tonic-clonic seizures (PGTCS): post hoc analysis of Phase II and III double-blind and open-label extension (OLEx) studies

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

<Notes to editors>

1. 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 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 and is being marketed in the United States and Europe.

Perampanel is currently approved in more than 55 countries, 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.