

No.15-84

December 2, 2015
Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA ON FYCOMPA® (PERAMPANEL) AT 69TH AMERICAN EPILEPSY SOCIETY ANNUAL MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the latest data on its in-house developed AMPA receptor antagonist Fycompa® (perampanel hydrate, "perampanel") will be presented at the 69th American Epilepsy Society (AES) Annual Meeting to be held from December 4 to 8 in Philadelphia in the United States.

For this year's AES meeting, poster presentations will be given on 22 abstracts with highlights including additional and pooled analyses on the results of global Phase III clinical studies on primary generalized tonic-clonic (PGTC) seizures in patients with generalized epilepsy (Study 332) and on partial-onset epilepsy (Study 304, Study 305, Study 306), as well as the results of a Phase III clinical study on partial-onset epilepsy conducted in Asia including Japan. Furthermore, the overall results of Study 332¹, Study 304² and Study 306³ were published in the major scientific journal *Neurology*, while the overall results of Study 305⁴ were published in the specialist epilepsy journal *Epilepsia*.

Perampanel is a first-in-class antiepileptic drug (AED) discovered and developed by Eisai. With epileptic seizures being primarily 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 postsynaptic AMPA receptors. Perampanel is approved in more than 45 countries including in Europe and North America, as well as countries in Asia such as Malaysia, Thailand, Philippines and South Korea, as an adjunctive treatment for partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy aged 12 years and older, and has been launched in more than 25 countries around the world under the brand name Fycompa. Furthermore, perampanel was approved for an indication expansion regarding the adjunctive therapy of PGTC seizures in patients from 12 years of age with generalized epilepsy in the United States and Europe in June 2015. Meanwhile, Eisai submitted a regulatory application for perampanel in Japan covering both PGTC seizures and partial-onset seizures (with or without secondarily generalized seizures) based primarily on Study 332 and Study 335 in July 2015.

Epilepsy affects nearly 1 million people in Japan, 2.9 million people in the United States, 6 million people in Europe, and more than 60 million people worldwide. Furthermore, over half of the people with epilepsy worldwide are estimated to live in Asia.⁵ As approximately 30% of patients with epilepsy are unable to sufficiently control their seizures with currently available AEDs,⁶ this is a disease with significant unmet medical needs. Eisai considers epilepsy a therapeutic area of focus and by providing multiple treatment options in addition to perampanel as part of an extensive epilepsy product portfolio, Eisai seeks to make continued contributions to address the diverse needs of, as well as increasing the benefits provided to, patients with epilepsy and their families.

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

- ¹ French JA, et al. Perampanel for tonic-clonic seizures in idiopathic generalized epilepsy. *Neurology* 2015; 85, 950–957
- ² French JA, et al. Adjunctive perampanel for refractory partial-onset seizures: randomized phase III study 304. *Neurology* 2012; 79, 589-596
- ³ Krauss GL, et al. Randomized phase III study 306: adjunctive perampanel for refractory partial-onset seizures. *Neurology* 2012; 78, 1408-1415
- ⁴ French JA, et al. Evaluation of adjunctive perampanel in patients with refractory partial-onset seizures: results of randomized global phase III study 305. *Epilepsia* 2013; 54, 117-125
- ⁵ Mac TL, et al. Epidemiology, aetiology, and clinical management of epilepsy in Asia: a systematic review. *Lancet Neurol* 2007;6:533–543
- ⁶ “The Epilepsies and Seizures: Hope Through Research. What are the epilepsies?” National Institute of Neurological Disorders and Stroke, accessed June 19, 2015, http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#230253109

Major Poster Presentations:

Abstract number	Abstract title
Abstract number: #1.184 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Effect of Adjunctive Perampanel in Pediatric Subjects With Epilepsy: Preliminary Safety and Efficacy Results From Study 232
Abstract number: #1.187 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Pharmacokinetics of Perampanel in Children with Epilepsy Aged 2 to12 Years
Abstract number: #1.188 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Efficacy of Perampanel by Baseline Seizure Frequency in Patients with Partial Seizures (Phase III Double-Blind Studies)
Abstract number: #1.189 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Suicidality Events in Patients With Primary Generalized Tonic-Clonic Seizures (PGTCS):A Review of Study 332
Abstract number: #1.190 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Psychiatric and Behavioral Events with Perampanel in Patients with Primary Generalized Tonic-Clonic Seizures (PGTCS): Study 332
Abstract number: #1.191 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Subanalysis by Baseline Antiepileptic Drugs (AEDs): Results From Perampanel Study 332 in Patients With Primary Generalized Tonic-Clonic Seizures (PGTCS)
Abstract number: #1.192 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Review of Pregnancy Events in Perampanel Clinical Studies
Abstract number: #1.193 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Effect of Duration of Epilepsy on Adjunctive Perampanel Treatment in Patients With Drug-Resistant Partial Seizures
Abstract number: #1.194 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Analysis of Falls in the Phase III Perampanel Study of Primary Generalized Tonic-Clonic Seizures (PGTCS)
Abstract number: #1.195 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Clinical Laboratory Evaluation and TEAEs Related to Cardiac, Hepatic and Renal Disorders: Perampanel PGTC Phase III Study

(continued on following page)

Abstract number	Abstract title
Abstract number: #1.196 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Long-Term Perampanel Treatment in Patients With Drug-Resistant Partial Seizures: ≥75% Responders and Seizure-Free Status
Abstract number: #1.211 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Model-predicted relationships between perampanel plasma concentrations and efficacy for partial-onset seizures (POS) and primary generalized tonic-clonic (PGTC) seizures
Abstract number: #1.212 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Protein Binding of Perampanel in Human Plasma: Does Protein-Binding Displacement Occur?
Abstract number: #1.214 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Pharmacokinetics of adjunctive perampanel in patients with partial-onset seizures and primary generalized tonic-clonic (PGTC) seizures in idiopathic generalized epilepsy (IGE): pooled data from four randomized, double-blind Phase III studies
Abstract number: #1.335 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Budget Impact of Perampanel for Treating Primary Generalized Tonic Clonic Seizures (PGTC) Patients in addition to existing Partial-Onset Seizures (POS) Patients in the US
Abstract number: #1.374 Saturday December 5 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Caregiver Burden: An Under-Recognized Aspect of Epilepsy Care
Abstract number: #2.239 Sunday December 6 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Effect of perampanel on neuroprotection in the lithium-pilocarpine rat model of status epilepticus
Abstract number: #2.250 Sunday December 6 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Efficacy and tolerability of perampanel in patients (pts) with secondarily generalized (SG) or primary generalized tonic-clonic seizures (PGTC): a pooled analysis of four randomized, Phase III studies
Abstract number: #2.263 Sunday December 6 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Efficacy and safety of adjunctive perampanel (PER) in adolescents with inadequately controlled partial-onset seizures (POS): randomized, double-blind and open-label extension (OLE) study
Abstract number: #3.256 Monday December 7 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	A randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of perampanel as adjunctive therapy in patients with refractory partial-onset seizures from the Asia-Pacific region
Abstract number: #3.260 Monday December 7 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Long-term cognitive effects of adjunctive perampanel (PER) in adolescents for treatment of partial-onset seizures (POS): randomized, double-blind and open-label extension (OLE) study
Abstract number: #3.262 Monday December 7 Poster presentation: 12:00-18:00 Poster discussion: 12:00-14:00	Effect of adjunctive perampanel on growth and development in adolescents with inadequately controlled partial-onset seizures (POS): randomized, double-blind and open-label extension (OLE) study