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Eisai Co., Ltd.

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

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the latest data on its antiepileptic drugs (AED) perampanel (product name: Fycompa®) and rufinamide (product name: Inovelon®, U.S. product name: BANZEL®) will be presented at the 2018 Annual American Academy of Neurology (AAN) Meeting to be held from April 21 to 27, 2018 in Los Angeles, California in the United States.

As major presentations, six poster presentations will be given for perampanel including on an analysis of clinical factors associated with maintaining long-term seizure freedom in global Phase III studies for adjunctive perampanel in patients with partial onset seizures (POS), as well as on an evaluation of perampanel as monotherapy using the results from these same Phase III studies. Regarding rufinamide, two poster presentations will be given including on an integrated analysis of clinical studies on rufinamide in patients with Lennox-Gastaut syndrome (LGS).

Perampanel is a first-in-class AED discovered at Eisai's Tsukuba Research Laboratories. It is available in tablet form to be taken once daily, and a new oral suspension formulation is also available in the United States. A highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at AMPA receptors, it is approved in countries around the world as an adjunctive therapy for the treatment of POS with or without secondarily generalized seizures, and primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy 12 years of age and older. Furthermore, perampanel is approved for use as monotherapy for POS in patients with epilepsy 12 years of age and older in the United States. In addition, Eisai has filed an application seeking approval for an indication expansion covering monotherapy and adjunctive use of perampanel in the treatment of POS with or without secondary generalized seizures in pediatric patients (2 years of age and older) in the United States.

Rufinamide is believed to exert its antiepileptic effects by regulating activity of voltage-gated sodium channels in the brain involved in the overexcitement of neurons that potentially causes seizures, so as to prolong their inactive state. The agent is approved as an adjunctive therapy to other AEDs in the treatment of seizures associated with LGS in Europe and the United States. In Japan, the agent is approved as an adjunctive therapy to other AEDs in the treatment of tonic and atonic seizures associated with LGS when therapy with other AEDs is considered inadequate.

Furthermore, regarding the anti-Aβ antibody aducanumab which is being jointly developed as of October 22, 2017 by Eisai and Biogen Inc. ("Biogen"), platform presentations will be made on long term administration of aducanumab in a Phase Ib clinical study currently being conducted by Biogen.

Eisai considers neurology including epilepsy, a therapeutic area of focus, and strives to provide new solutions for those living with epilepsy and increase the breadth of patients for which perampanel may provide seizure-freedom in order to further contribute to addressing the diverse needs of, as well as increasing the benefits provided to, patients with epilepsy and their families.

Major poster presentations for perampanel:

| Poster number | Abstract title |
|---|---|
| **Poster number: 259**<br>*Sunday April 22*<br>*Poster presentation: 16:00-17:30* | Extrapolation of Adjunctive Efficacy and Safety Data from Phase III Partial Epilepsy Trials to Evaluate Perampanel as Monotherapy |
| **Poster number: 260**<br>*Sunday April 22*<br>*Poster presentation: 16:00-17:30* | Clinical Factors Associated with a Major Response (≥75% Reduction in Seizure Frequency/28 Days) in Phase III Trials of Adjunctive Perampanel in Patients with Partial Seizures: Post Hoc Multivariate Analysis |
| **Poster number: 261**<br>*Sunday April 22*<br>*Poster presentation: 16:00-17:30* | Effect of Common Concomitant Antiepileptic Drugs (AEDs) During Adjunctive Treatment with Perampanel: Post Hoc Analysis from the Open-Label Extension (OLEx) of a Phase III Study in Patients with Idiopathic Generalized Epilepsy (IGE) |
| **Poster number: 267**<br>*Sunday April 22*<br>*Poster presentation: 16:00-17:30* | Retrospective, Phase IV Study of Perampanel in Real-World Clinical Care of Patients with Epilepsy: An Interim Analysis |
| **Poster number: 268**<br>*Sunday April 22*<br>*Poster presentation: 16:00-17:30* | Assessment of the Long-Term Efficacy and Safety of Adjunctive Perampanel in Adolescent Patients: Post Hoc Analysis of Open-Label Extension (OLEx) Studies |
| **Poster number: 270**<br>*Sunday April 22*<br>*Poster presentation: 16:00-17:30* | Time to Pre-Randomization Monthly Seizure Count for Perampanel in Patients with Primary Generalized Tonic-Clonic (PGTC) Seizures: A Potential New Clinical Endpoint |

Major poster presentations for rufinamide:

| Poster number | Abstract title |
|---|---|
| **Poster number: 272**<br>*Sunday April 22*<br>*Poster presentation: 16:00-17:30* | Post Hoc Analysis of Rufinamide Study 303: Seizure-Free Days in Patients with Lennox-Gastaut Syndrome (LGS) |
| **Poster number: 273**<br>*Sunday April 22*<br>*Poster presentation: 16:00-17:30* | Efficacy and Safety of Adjunctive Rufinamide in Lennox-Gastaut Syndrome (LGS): Results from Studies 022, 022E, 303, 304, and 305 |

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