EISAI PRESENTS RESULTS FROM PHASE III TRIAL OF ANTIEPILEPTIC DRUG

days in the Maintenance period relative to baseline) was observed for perampanel compared to placebo. The results of the analysis showed that both change in PGTC seizure frequency and responder rate for Asia-Pacific region patients (42 patients) were similar to the total patient population results already presented, and there were no large regional differences in the incidence of adverse events.

Perampanel is a first-in-class 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, the Philippines and South Korea, as an adjunctive treatment for partial-onset seizures (with or without secondary generalized seizures) in patients with epilepsy aged 12 years and older, and has been launched in 25 countries around the world under the Fycompa brand name. 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 U.S. and Europe in June 2015.

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

2. About Study 335

Study title:	A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Perampanel Administered as an Adjunctive Therapy in Subjects with Refractory Partial-onset Seizures
Study population:	710 patients aged 12 years and older with partial-onset seizures receiving one to a maximum of three anti-epileptic drugs
Treatment administered:	Perampanel oral tablets, 4 mg/day, 8 mg/day or 12 mg/day, or placebo, once daily.
Duration of treatment:	Prerandomization Phase: 6 weeks; Randomization Phase: 19 weeks (Titration Period, 6 weeks; Maintenance Period, 13 weeks) Extension Phase: over 10 weeks
Study locations:	Japan, China, South Korea, Australia, Thailand, Malaysia, Taiwan
Primary endpoint:	Percent change in seizure frequency (per 28 days in the randomization phase relative to the pre-randomization phase)
Results:	-The percent change in seizure frequency in the placebo group was -10.8% while in the perampanel (4 mg, 8 mg, 12 mg) groups it was -17.3%, -29.0% and -38.0 %, respectively. The difference between perampanel and placebo was statistically significant for the perampanel 8 and 12 mg groups (p=0.0003 for 8 mg, p<0.0001 for 12 mg). -As the study's secondary endpoint, the responder rate (percentage of patients who had at least a 50% reduction in seizure frequency in the Maintenance Period of the Randomization phase relative to the Prerandomization Phase) in the placebo group was 19.4% while in the perampanel (4 mg, 8 mg, 12 mg) groups it was 23.0%, 36.0% and 43.3%, respectively, and the difference between perampanel and placebo was statistically significant in the perampanel 8 mg and 12 mg groups (p=0.0005 for 8 mg, p<0.0001 for 12 mg). -As another of the study's secondary endpoints, the percent change in seizure frequency of secondarily generalized seizures in the placebo group was -12.1% while in the perampanel (4 mg, 8 mg, 12 mg) groups it was -17.9%, -45.0% and -52.5%, respectively.
Adverse events:	The most common adverse events (>10% in the perampanel arms) were dizziness, somnolence and nasopharyngitis.

3. About Study 332[1]

Study title:	A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Adjunctive Perampanel in PGTC Seizures
Study population:	164 patients aged 12 years and older with PGTC seizures receiving one to a maximum of three anti-epileptic drugs
Treatment administered:	(Placebo-controlled) Perampanel oral tablets, once daily, up to 8 mg/day (Titration Period), randomized dose 8 mg/day (Maintenance Period).
Duration of treatment:	Prerandomization Phase (Screening and Baseline Periods): up to 12 weeks Randomization Phase (treatment): 17 weeks (Titration Period, 4 weeks; Maintenance Period, 13 weeks) Extension Phase: over 38 weeks
Study locations:	U.S., Europe, Japan, Asia

Primary endpoint:	Percent change in PGTC seizure frequency (percent change from baseline in PGTC seizure frequency per 28 days during treatment)
Results:	-The percent change in PGTC seizure frequency observed for the perampanel group was -76.5%, which was statistically significant when compared to -38.4% for the placebo group ($p<0.0001$). -The responder rate (percentage of patients who experience a 50% or greater reduction in PGTC seizure frequency per 28 days in the Maintenance period relative to baseline) for the perampanel group was 64.2%, which was a statistically significant improvement over the responder rate for the placebo group of 39.5% ($p=0.0019$). -For patients who had been unable to adequately control PGTC seizures with existing AEDs, 30.9% of patients treated with perampanel were free of PGTC seizures (12.3% for placebo) during the 13 week Maintenance period.
Adverse events:	The most common adverse events (>10% in the perampanel group and greater than placebo) for perampanel and placebo were, respectively, dizziness, fatigue, headache, somnolence and irritability.
Sub-group analysis results:	-In the Asia-Pacific sub-group (42 patients), the percent change in PGTC seizure frequency was -66.8% for the perampanel group and -38.4% for the placebo group, while the responder rate was 59.5% for the perampanel group and 40.5% for the placebo group, which was consistent with the overall results. No large