



**EISAI' S IN-HOUSE DEVELOPED ANTIEPILEPTIC DRUG FYCOMPA®  
(PERAMPANEL HYDRATE) APPROVED IN JAPAN AS ADJUNCTIVE THERAPY FOR  
PARTIAL-ONSET**



### 3. About Study 335<sup>1</sup>

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 who have a diagnosis of epilepsy with partial-onset seizures with or without secondarily generalized seizures receiving one to a maximum of three anti-epileptic drugs

Treatment administered:

Perampanel oral tablets, 4 mg/day, 8 mg/day and 12 mg/day, once daily before bedtime  
Perampanel-matched placebo oral tablets, once daily before bedtime

Duration of treatment:

Prerandomization Phase: 6 weeks

Randomization Phase (treatment): 19 weeks

(Titration Period, 6 weeks; Maintenance Perampanel 12 mg/day once daily before bedtime)

-The responder rate for perampanel was 64.2%, which was a statistically significant improvement over 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 placebo of 39.5% (p=0.0019).

