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

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Study 311 (NCT02849626) assessed safety, tolerability, pharmacokinetics and efficacy of once-daily adjunctive perampanel oral suspension in patients aged 4 to <12 years with POS (with/without secondarily generalised seizures [SGS]) or primary generalised tonic-clonic seizures. Here, we report Core Study safety and efficacy data stratified by concomitant Baseline EIASD use. The Core Study consisted of 4-week Pre-treatment, 23-week Treatment and 4-week Follow-up Periods. Patients must have been on stable doses of 1–3 concomitant ASDs; 1 EIASD (carbamazepine, oxcarbazepine, eslicarbazepine or phenytoin) was permitted. Perampanel was titrated to ≤16 mg/day for EIASD and ≤12 mg/day for non-EIASD patients (≤12 mg/day in Japanese patients, irrespective of EIASD status). In total, 180 patients (EIASD, n=48; non-EIASD, n=132) received ≥1 perampanel dose. The most common EIASDs were carbamazepine (14%) and oxcarbazepine (11%). Treatment-emergent adverse events were reported in 40 (83.3%) patients with and 120 (90.9%) patients without EIASDs; most common were somnolence and nasopharyngitis. Median percent reduction in seizure frequency per 28 days from Baseline with vs without EIASDs was 34.0% vs 42.2%, respectively, for POS, and 59.5% vs 57.8%, respectively, for SGS. 50% responder rates were similar between patients with vs without EIASDs (POS: 45.7% vs 47.1%; SGS: 54.5% vs 67.4%, respectively). Seizure-freedom rates with vs without EIASDs were 10.9% vs 11.8%, respectively, for POS, and 9.1% vs 20.9%, respectively, for SGS. In this subanalysis, adjunctive perampanel was generally well tolerated and efficacious in patients aged 4 to <12 years with POS, with/without SGS, regardless of Baseline concomitant EIASD status.

Biography

Leock Y. Ngo has a PhD in Pharmaceutical Sciences from the University of Alberta, Canada and was a Postdoctoral Research Fellow at the University of Washington in Seattle, Washington. Stella is Director in Clinical Research at Eisai Inc., responsible for the development of new anti-epilepsy drugs. She is the International Project Lead for Fycompa® and Inovelon®, and the Clinical Lead for new chemical entities in early development for epilepsy treatment. Before joining Eisai, Stella gained 19+ years' experience in clinical pharmacology and clinical trials across various therapeutic areas, including neurology (Alzheimer's disease and peripheral neuropathy), oncology, pulmonology and autoimmune/inflammatory disorders.

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