Safety and efficacy of adjunctive perampanel in younger (aged 4 to <7 years) and older (aged 7 to <12 years) paediatric patients with partial-onset seizures (POS) or primary generalised tonic-clonic seizures (PGTCS): 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 PGTCS. Here, we report core study safety and efficacy data stratified by age (Cohort 1: 4 to <7 years; Cohort 2: 7 to <12 years). The core study included 4-week pre-treatment, 23-week treatment and 4-week follow-up periods. Primary endpoints were safety and tolerability. Secondary endpoints included median percent change in seizure frequency per 28 days from baseline, and 50% responder and seizure-freedom rates during maintenance. In total, 180 patients received ≥1 perampanel dose (Cohort 1: n=46; Cohort 2: n=134). Treatment-emergent adverse events were reported by 45 (97.8%; Cohort 1) and 115 (85.8%; Cohort 2) patients; most common were somnolence, nasopharyngitis, dizziness and irritability. Full analysis set, cohort 1 vs., 2: POS, n=40 vs 108; SGS, n=17 vs 37; PGTCS, n=3 vs 19, respectively. Median percent reduction in seizure frequency per 28 days from baseline for POS, PGTCS and SGS, Cohort 1 vs 2: 42.7%, 56.5%, 56.3% vs 40.1%, 81.9%, 60.6%, respectively. 50% responder rates were similar between cohorts for POS, PGTCS and SGS (Cohort 1: 45.0%, 66.7%, 70.6% vs., cohort 2: 47.2%, 63.2%, 62.2%, respectively). Seizure-freedom rates for POS, PGTCS and SGS, Cohort 1 vs., 2: 7.5%, 66.7%, 17.6% vs., 13.0%, 52.6%, 18.9%, respectively. Adjunctive perampanel was generally well tolerated and efficacious in patients 4 to <7 and 7 to <12 years with POS, PGTCS or SGS.

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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