Safety and efficacy of adjunctive perampanel in paediatric patients (aged 4 to <12 years) with partial-onset seizures (POS) or primary generalised tonic-clonic seizures (PGTCS): Final results from the 311 core study

Leock Y. Ngo[1], Robert Flamini[2], Andras Fogarasi[3], Mathieu Milh[4], Steven Phillips[5], Shinsaku Yoshitomi[6], Anna Patten[7], Takao Takase[8] and **Antonio Laurenza[1]**

[1]Eisai Inc., USA
[2]Pediatric and Adolescent Neurodevelopmental Associates, USA
[3]Epilepsy Centre, Bethesda Children's Hospital, Hungary
[4]La Timone-Enfants Hospital, France
[5]Mary Bridge Children's Neurology Clinic, USA
[6]Shizuoka Institute of Epilepsy and Neurological Disorders, Japan
[7]Eisai Ltd., UK
[8]Eisai Co., Ltd., Japan

Perampanel is a once-daily oral anti-seizure drug for POS and PGTCS. Study 311 (NCT02849626) is a global, multicentre, open-label, single-arm study assessing the 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. We report safety, tolerability and efficacy data from the 311 Core Study. This study included a 4-week Pre-treatment Period, 23-week Treatment Period and 4-week Follow-up Period. Primary endpoints were safety and tolerability. Secondary endpoints included median percent change in seizure frequency per 28 days from Baseline during the Treatment Period, and 50% responder and seizure-freedom rates during Maintenance (Core Study) and longer-term treatment (≤52 weeks). In total, 180 patients (POS, n=149; PGTCS, n=31) received ≥1 perampanel dose (mean age [standard deviation], 8.1 [2.09] years; female, 48.9%); 146 (81.1%) patients completed the Core Study and 34 (18.9%) discontinued. Adverse events (AEs) were the primary reason for discontinuation (n=14 [7.8%]). Median (minimum, maximum) dose of perampanel was 8.0 (2, 16) mg/day and duration of exposure was 22.9 (0, 27) weeks. Treatment-emergent AEs in ≥10% of patients were: somnolence, nasopharyngitis, dizziness, irritability, pyrexia and vomiting. Median percent reduction in seizure frequency per 28 days from Baseline, 50% responder rates and seizure-freedom rates, respectively, were: POS: 40.1%, 46.6% and 11.5%; PGTCS: 69.2%, 63.6% and 54.5%; SGS: 58.7%, 64.8% and 18.5%. Adjunctive perampanel was generally safe, well tolerated and efficacious in children aged 4 to <12 years with POS, SGS or PGTCS.

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.

Stella_Ngo@eisai.com