Study 506 – third interim analysis of a retrospective, phase IV study of perampanel in real-world clinical care of patients with epilepsy: Paediatric subgroup (aged <12 years)

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Perampanel is given daily once orally as anti-seizure drug for partial-onset seizures (POS) and primary generalised tonic clonic seizures. We report second interim results for paediatric patients from the multicentre, non-interventional, Phase IV, retrospective study 506 (NCT03208660), to assess retention rate, safety and dosing experience of perampanel administered to patients with epilepsy during routine clinical care. Data were obtained from medical records of patients initiating perampanel after 1 January 2014. Primary endpoint is retention rate (proportion of patients in Safety Analysis Set [SAS] remaining on perampanel). Safety, efficacy and dosing experience are secondary objectives. Interim SAS comprised 605 patients; 68 were aged <12 years (mean age [standard deviation (SD)], 6.7[3.0] years). Seizure types included: complex partial, n=33 (48.5%); POS with secondary generalization, n=11(16.2%); generalized tonic-clonic, n=21 (30.9%). Mean (SD) cumulative duration of exposure to perampanel was 14.3(11.5) months and mean (SD) maximum perampanel dose was 5.4(3.2) mg. At data cut-off (5 March 2018), 34(50.0%) paediatric patients remained on perampanel 33(48.5%) had discontinued, primarily due to adverse event (AE; n=15 [22.1%]) and inadequate therapeutic effect (n=11 [16.2%]). Retention rates at 3, 6, 12, 18 and 24 months were 82.4% (n=56/68), 66.2% (n=43/65), 61.0% (n=36/59), 53.2% (n=25/47) and 48.6% (n=17/35), respectively. Treatment emergent AEs occurred in 39.7% of patients; most common were abnormal behavior, aggression and irritability (all 5.9%). This subgroup analysis suggests that daily oral doses of adjunctive perampanel are generally well tolerated, with favorable retention rates for ≤2 years in pediatric patients (<12 years) with epilepsy.

Biography

Manoj Malhotra received his Medical Degree from Wayne State University in Detroit, Michigan. He completed his Neurology residency and two fellowships at The Cleveland Clinic in Cleveland, Ohio. He is the Vice President, Head of Medical Affairs for the Neurology Business Group at Eisai Inc. He is responsible for Medical Affairs activities for the Americas and is Global Medical Lead for Epilepsy. He holds six neurology board certifications (neurology, epilepsy, sleep medicine, clinical neurophysiology, vascular neurology and electrodiagnostic medicine) and has extensive experience in neurodegenerative diseases, rare diseases and epilepsy. His industry experience includes working at Novartis, Takeda and Mallinckrodt.

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