Study 506 – third interim analysis of a retrospective, phase IV study of perampanel in real-world clinical care of patients with epilepsy: Adolescent subgroup (aged 12-<18 years)

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Perampanel is a once-daily oral anti-seizure drug for partial-onset seizures (POS) and primary generalised tonic-clonic seizures. We report second interim results for adolescent 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; 101 were aged 12-<18 years (mean age [standard deviation (SD)], 14.6 [1.8] years; 50.5% female). Seizure types included: complex partial, n=51 (50.5%); POS with secondary generalisation, n=31 (30.7%); generalised tonic-clonic, n=46 (45.5%). The mean (SD) perampanel dose was 5.7 (2.3) mg, and the mean (SD) maximum perampanel dose was 6.6 (3.4) mg. At data cut-off (5 March 2018), 52 (51.5%) adolescent patients remained on perampanel and 49 (48.5%) had discontinued, mainly due to adverse event (AE; n=30 [29.7%]) and inadequate therapeutic effect (n=16 [15.8%]). Retention rates at 3, 6, 12, 18 and 24 months were 77.2% (n=78/101), 69.0 (n=69/100), 55.6% (n=50/90), 49.3% (n=35/71) and 52.9% (n=27/51), respectively. Treatment-emergent AEs occurred in 48.5% of patients, including aggression (8.9%), somnolence (7.9%) and irritability (5.9%). This subgroup analysis suggests daily oral doses of adjunctive perampanel are generally well tolerated, with favourable retention rates for ≤2 years in adolescent patients (aged 12-<18 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. Manoj is 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 6 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. Manoj's industry experience includes working at Novartis, Takeda and Mallinckrodt.

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