N-MOmentum (NCT02200770) open-label period (OLP) vs azathioprine and other immunosuppressants (AZA/IST) and vs PBO. Methods: Two historical comparator groups (HCGs), AZA/IST (N=132) and PBO (N=106), derived from published NMOSD studies, were used to compare efficacy of INEB (N=208) over the OLP. Hazard ratios (HR) for INEB vs HCGs were estimated using Cox proportional hazards (PH) regression. Time to NMOSD attack was analysed using parametric and flexible survival (spline) models. Results: Time to NMOSD attack for N-MOmentum PBO compared to PBO was HR 1.15;(95% CI:0.67–1.91; *P*=0.58). The HRs for time to NMOSD attack for INEB vs AZA/IST and PBO groups were 0.29(95% CI:0.17, 0.42; *P*<0.001) and 0.15 (95% CI:0.10, 0.21; *P*<0.001). At 4 years, estimated attack-free survival was 77% (95% CI:71, 83) for INEB, 36% (95% CI:27, 46) for AZA/IST, and 12% (95% CI:7, 20) for PBO. Conclusions: INEB was associated with a statistically significant reduction in risk of an NMOSD attack and provided a long-term attack-free probability over the OLP compared to the relative short-term benefit observed with AZA/IST.

P.010

Safety and efficacy of inebilizumab in AQP4+ NMOSD participants with history of immunosuppression treatment prior to N-MOmentum study

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Background: The long-term outcomes of inebilizumab in participants from the N-MOmentum trial with a history of immunosuppressant therapy as compared to those without was evaluated. Methods: N-MOmentum (NCT02200770) was a 28-week randomized phase 2/3 trial of inebilizumab vs placebo, with an optional Open-Label Period (OLP) (>2 years). In this post hoc analysis, $AQP4^+$ participants who received inebilizumab (through the OLP) were grouped by no history of immunosuppression therapy beyond treatment of acute NMOSD attacks (naïve), or prior azathioprine (AZA) and/or mycophenolate mofetil (MMF) therapy. Results: Among participants who received inebilizumab during the study, 94 received prior AZA/MMF and 103 were immunosuppressant naïve. Annualized relapse rate (95%CI) for participants with prior AZA/MMF was 0.11 (0.07, 0.17), compared to 0.08 (0.05, 0.14) for naïve. The hospitalization rate (annualized rate [95% CI]) for prior AZA/MMF was 0.15 (0.08, 0.27), and 0.12 (0.06, 0.22) for naïve. Participants with ≥1 study drug-related-treatment-emergent-adverse-event (TEAE) was 30.9% (29/94) in prior AZA/MMF and 46.6% (48/103) of naïve. Most adverse events were infection-related for both groups; 72.3% (68/94) for prior AZA/MMF and 77.7% (80/94) for naïve. Conclusions: This post hoc analysis evaluating long-term outcomes of inebilizumab in $AQP4^+$ NMOSD participants treated with prior AZA/MMF therapy demonstrated a similar efficacy and safety profile as participants without prior immunosuppressant therapy.

P.011

Efficacy and safety of ravulizumab in adults with AQP4+ NMOSD: interim analysis from the ongoing phase 3 CHAMPION-NMOSD trial

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Background: CHAMPION-NMOSD (NCT04201262) is an ongoing global, open-label, phase 3 study evaluating ravulizumab in AQP4+ NMOSD. Methods: Adult patients received an intravenous, weight-based loading dose of ravulizumab on day 1 and a maintenance dose on day 15 and every 8 weeks thereafter. Following a primary treatment period (PTP; up to 2.5 years), patients could enter a long-term extension (LTE). Results: 58 patients completed the PTP; 56/2 entered/completed the LTE. As of June 16, 2023, median (range) follow-up was 138.4 (11.0-183.1) weeks for ravulizumab (n=58), with 153.9 patient-years. Across the PTP and LTE, no patients had an adjudicated on-trial relapse during ravulizumab treatment. 91.4% (53/58 patients) had stable or improved Hauser Ambulation Index score. 91.4% (53/58 patients) had no clinically important worsening in Expanded Disability Status Scale score. The incidence of treatment-emergent adverse events (TEAEs) and serious adverse events was 94.8% and 25.9%, respectively. Most TEAEs were mild to moderate in severity and unrelated to ravulizumab. TEAEs leading to withdrawal from ravulizumab occurred in 1 patient. Conclusions: Ravulizumab demonstrated long-term clinical benefit in the prevention of relapses in AQP4+ NMOSD with a safety profile consistent with prior analyses.

P.012

A global, long-term, prospective, observational registry of patients with AQP4+ NMOSD treated with complement component 5 inhibitor therapies eculizumab or ravulizumab

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Background: The complement component 5 inhibitor therapies (C5ITs) eculizumab and ravulizumab have been approved or submitted for regulatory approval in several regions for AQP4+ NMOSD. Methods: This global, long-term, prospective, multicenter, observational registry will enroll adult patients with AQP4+ NMOSD being treated with eculizumab or ravulizumab and who have received ≥1 dose of eculizumab or ravulizumab within 4 or 12 weeks prior to enrollment, respectively. Inclusion criteria include available historical data on C5IT dosing since initiation and the number and types of relapses from 1 year prior to C5IT initiation