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# Efficacy and Safety of Satralizumab for Relapse Prevention in Neuromyelitis Optica Spectrum Disorder: A Pooled Analysis from Two Phase 3 Clinical Trials

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**Background:** Satralizumab is a humanised recycling monoclonal antibody that binds to the interleukin-6 (IL-6) receptor; IL-6 has been implicated in the pathophysiology of neuromyelitis optica spectrum disorder (NMOSD). Satralizumab significantly reduced the risk of NMOSD relapse in two Phase 3 studies: SAkuraSky (SA-307JG; NCT02028884) and SAkuraStar (SA-309JG; NCT02073279). Hazard ratios (HR) for the risk reduction were 0.38 (95% confidence interval [CI] 0.16–0.88) in SA-307JG and 0.45 (95% CI 0.23–0.89) in SA-309JG (both p=0.018). Satralizumab was particularly effective in AQP4-IgG-seropositive patients (HR 0.21 [95% CI 0.06–0.75] in SA-307JG and HR 0.26 [95% CI 0.11–0.63] in SA-309JG).

**Method(s):** Patients were randomized 1:1 (SA-307JG) or 2:1 (SA-309JG) to satralizumab (120 mg) or placebo, with treatment at Weeks 0, 2, 4, and Q4W thereafter. Satralizumab or placebo were administered as monotherapy (SA-309JG) or add-on to baseline immunosuppressants (SA-307JG). The primary endpoint of both studies and the pooled analysis was time to first protocol-defined relapse (PDR). Efficacy analyses were performed on the pooled intention-to-treat population. Between-group HRs for time to PDR were calculated based on Cox proportional hazards models, stratified by study. To assess the validity of pooling data across the two studies, individual study treatment effects within the pooled analysis and study by treatment interaction effect were calculated.

**Result(s):** The pooled analysis included 104 patients who received satralizumab and 74 who received placebo. HR for time to first PDR was 0.42 (95% CI 0.25–0.71; 58% risk reduction vs placebo). For AQP4-IgG seropositive patients, the HR was 0.25 (95% CI 0.12–0.50; 75% risk reduction); in the seronegative group, the HR was 0.97 (95% CI 0.41–2.23). The validity of pooling the data was confirmed, as no interaction between study and treatment effect was observed. Incidence of adverse events was similar in satralizumab and placebo groups; there were no deaths or anaphylactic reactions.

**Conclusion:** This pooled analysis of data from two Phase 3 studies demonstrated the efficacy of satralizumab in reducing relapse risk in patients with NMOSD. Satralizumab had a favourable safety profile as monotherapy or alongside immunosuppressants.