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Long-term efficacy of satralizumab in patients with AQP4-IgG+ NMOSD: Updated analysis from the open-label SAkuraMoon study

Jacqueline Palace * [1],Anthony Traboulsee [2],Albert Saiz [3],Jérôme De Seze [4],Ingo Kleiter [5],Jeffrey L. Bennett [6],Daniela Stokmaier [7],Gaelle Klingelschmitt [7],Audrey Yeo Te-Ying [7],Ivana Vodopivec [7],Takashi Yamamura [8],

[1] John Radcliffe Hospital, Oxford, United Kingdom, [2] University of British Columbia, Vancouver, Canada, [3] Service of Neurology, Hospital Clinic and August Pi i Sunyer Biomedical Research Institute, University of Barcelona, Barcelona, Spain, [4] Hautepierre Hospital, Strasbourg, France, [5] Ruhr University Bochum, Bochum, Germany, [6] University of Colorado School of Medicine, Aurora, United States, [7] F. Hoffmann-La Roche Ltd, Basel, Switzerland, [8] National Center of Neurology and Psychiatry, Tokyo, Japan

Introduction:

Satralizumab (SAT) significantly reduced the risk of protocol-defined relapse (PDR) in 2 pivotal phase 3 trials in patients with neuromyelitis optica spectrum disorder (NMOSD): SAkuraSky (NCT02028884; SAT + baseline immunosuppressants [IST]) and SAkuraStar (NCT02073279; SAT monotherapy).

Objectives/Aims:

To assess the long-term efficacy of SAT in patients with aquaporin-4-IgG-seropositive (AQP4 IgG+) NMOSD.

Methods:

Patients who completed the double-blind periods (DBPs) and open-label extensions (OLEs) of SAkuraSky and SAkuraStar were rolled-over into SAkuraMoon (NCT04660539), a single-arm, open-label study, and continued receiving SAT 120mg Q4W +/- IST. Efficacy analyses are based on the overall SAT treatment period, from patients' first dose in the DBPs of SAkuraSky and SAkuraStar to the clinical cut-off date of 31 January 2023. PDRs were adjudicated by a Clinical Endpoint Committee in the DBPs and were determined by the investigator (iPDRs) in the OLEs and SAkuraMoon. Key analyses included annualised iPDR rate (ARR), time to first iPDR, severe iPDR (≥2 point increase in the Expanded Disability Status Scale [EDSS] score), and sustained EDSS worsening (EDSS increase of ≥2, ≥1, or ≥0.5 points for patients with baseline scores of 0, 1–5, or ≥5.5, respectively, confirmed ≥24 weeks post-initial-worsening).

Results:

Overall, 111 AQP4+ patients were included. The median (range) duration of SAT exposure was 5.9 (0.1–8.9) years. The overall adjusted ARR (95% CI) was 0.08 (0.06–0.10), where the ARR did not increase with additional years of exposure (Y1: 0.17 [0.10–0.28]; Y2: 0.10 [0.05–0.19]; Y3: 0.04 [0.01–0.14]; Y4: 0.08 [0.02–0.25]; Y5: 0.05 [0.01–0.17]). At Week 288 (5.5 years), 72% (95% CI: 62–80%) of SAT-treated patients were free from iPDR, 91% (83–95%) were free from severe iPDR, and 83% (73–90%) had no sustained EDSS worsening. 3 patients dropped out from SAkuraMoon; 2 patients switched to commercial satralizumab and 1 patient discontinued treatment due to pregnancy.

Conclusion:

These results demonstrate the effective long-term management of NMOSD with SAT over 5.5 years of treatment. The ARR remained consistently low in SAT-treated patients, with high proportions of patients remaining free from relapse, severe relapse, and worsening in disability.

Disclosures:

AT received consulting fees from Genzyme, Roche, and Novartis and is part of a speaker's bureau for Genzyme and Roche.

AS received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Merck Serono, Sanofi, Biogen, Roche, Teva, Novartis, Alexion, and Janssen.

JDS received grants and personal fees from Roche and Chugai and has served on advisory boards in the expert committee for the clinical trial conducted by Chugai.

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DS, GK, AYT and IV are all full-time employees of F. Hoffmann La-Roche Ltd.

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