

Ocrelizumab, serum immunoglobulin levels and serious infections

SI and IgG analyses are presented for the Phase III OPERA (RMS) and ORATORIO (PPMS) populations only

Overview^{1,2}

- After 11 years of continuous OCR treatment, IgG levels remained above the LLN for >80% of patients with RMS and PPMS
- During episodes of IgG<LLN, the type, severity and outcome of SIs were consistent with the overall SIs observed in patients treated with ocrelizumab during the controlled period and OLE phase

Clinical trial population: Relationship between SI rates and Ig levels³

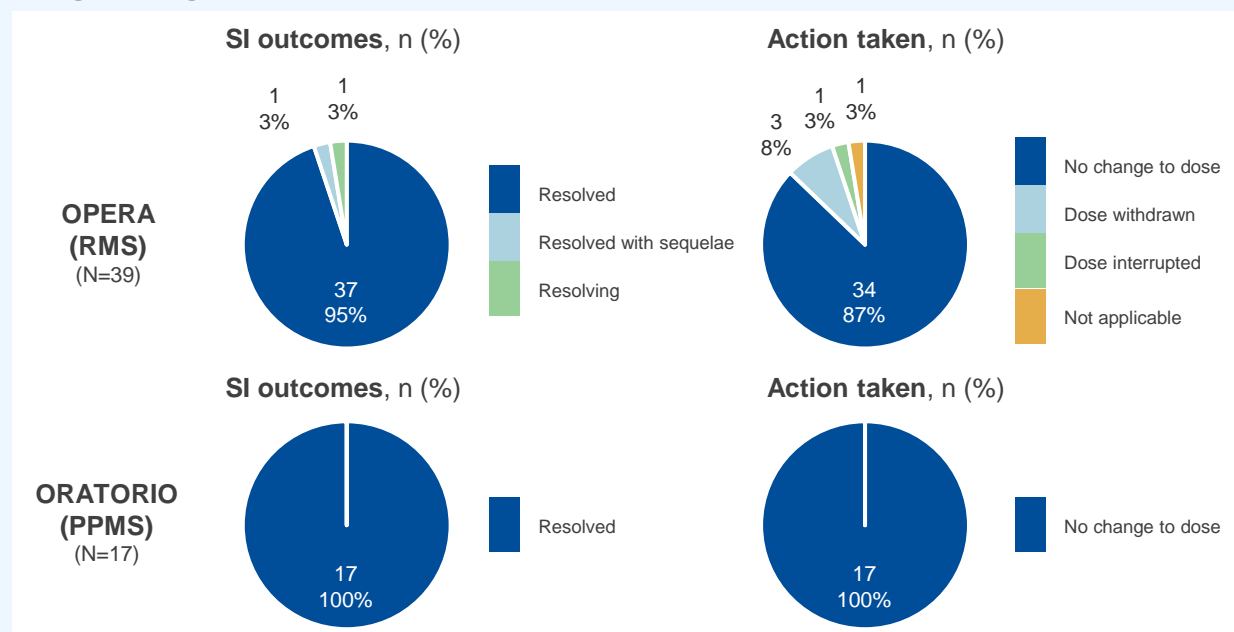
COVID-19 related AEs were excluded from this analysis, but patients continued to contribute to the incidence of all other AEs

- Based on a multivariate analysis, there is a weak association between IgG and risk of SIs
- Other risk factors include comorbidities, disability progression, on-study relapses, increased BMI and abnormal IgM levels

SIs associated with low IgG levels by MS type: OPERA (RMS) and ORATORIO (PPMS)²

- During a period with IgG<LLN, **2.0%** of patients with RMS and **1.9%** of patients with PPMS had an SI
- **UTIs, LRTIs, sepsis, abdominal and GI infections, and skin infections were the most common SIs** associated with episodes of IgG<LLN, a pattern similar to overall SIs

Figure 1: IgG<LLN and SIs: Outcome and action taken with OCR²



- During periods of IgG<LLN, there were **no fatal events**, most SIs resolved and treatment with OCR was continued in almost all cases

For more information on the rate of infections with OCR treatment, please visit the [Ocrelizumab and infections](#)

Footnotes

Figure 1: n indicates the number of events. Percentages may not total 100% due to rounding. SI and IgG analyses are presented for the Phase III OPERA (RMS) and ORATORIO (PPMS) populations only. **Abbreviations:** AE, adverse event; BMI, body mass index; COVID-19, coronavirus disease 2019; Ig, immunoglobulin; GI, gastrointestinal; LLN, lower limit of normal; LRTI, lower respiratory tract infection; OCR, ocrelizumab; OLE, open-label extension; PPMS, primary progressive MS; RMS, relapsing MS; SI, serious infection; UTI, urinary tract infection.

Reference

1. Hauser SL, et al. Presented at ECTRIMS 2023 (Poster P304); 2. Hauser SL, et al. Presented at ECTRIMS 2024 (Poster P300); 3. Derfuss T, et al. *Ther Adv Med Oncol* 2024;17:10.1177/17562864241277736.

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