

Effect of Ofatumumab on Serum Immunoglobulin Levels and Infection Risk in Relapsing Multiple Sclerosis Patients from the Phase 3 ASCLEPIOS I and II Trials

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INTRODUCTION

Ofatumumab, the first fully human anti-CD20 monoclonal antibody, demonstrated superior efficacy versus teriflunomide in relapsing multiple sclerosis (RMS) patients in the ASCLEPIOS I/II trials. This study investigated serum immunoglobulin (Ig)G and IgM levels, and their associations with risk of infections in ofatumumab-treated patients.

METHODS

Patients received subcutaneous ofatumumab 20 mg on Days 1, 7, and 14, Week 4, and every 4 weeks thereafter or oral teriflunomide 14 mg once-daily for up to 30 months (average follow-up: 18 months). Serum IgG/IgM levels were monitored at baseline, Weeks 4 and 12, and every 12 weeks thereafter (ofatumumab, n=946; teriflunomide, n=936). We assessed the proportion of patients with IgG/IgM levels <50% of lower limit of normal (LLN [g/L]; IgG [3.5], IgM [0.2]), and association between low IgG/IgM levels and infection rates.

RESULTS

At Week 120, no patients reached IgG levels <50%LLN with ofatumumab (ASCLEPIOS I and II, median[g/L]: 10.57 and 9.57, respectively) or teriflunomide (10.01 and 9.65). Proportion of patients with IgM levels <50%LLN was 2.1% (n=20/944) for ofatumumab (median[g/L]: 0.91 and 0.59) and 0.6% (n=6/933) for teriflunomide (0.84 and 0.92) at Week 120. Of these, five

ofatumumab-treated patients experienced infections, mostly non-serious (Grade-1/2), except one recurrent urinary tract infection (Grade-3); all infections were resolved. One patient on teriflunomide who experienced nasopharyngitis had not recovered at the time of last follow-up.

CONCLUSIONS

No reduction in serum IgG levels <50% LLN was observed with either treatment, while IgM levels decreased with both treatments; there was no apparent association with increased rate of serious/non-serious infections in RMS patients.

Disclosure:

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SUBMISSION REQUIREMENTS

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