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MULTIPLE SCLEROSIS: CLINICAL TRIALS AND THERAPEUTICS (INCLUDING SAFETY) 2 | April 9, 2024 |

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# Long-term Effect of Ofatumumab on Serum Immunoglobulin Levels in Patients with Relapsing Multiple Sclerosis (P9-6.007)

[Amit Bar-Or](#), [Heinz Wiendl](#), [Jerome De Seze](#), [Jorge Correale](#), [Anne Cross](#), [Tobias Derfuss](#), [Krzysztof Selmaj](#), ... [SHOW ALL ...](#), and [Stephen Hauser](#) | [AUTHORS INFO & AFFILIATIONS](#)

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## Abstract

### Objective:

Evaluate the effect of ofatumumab on serum immunoglobulin (Ig) levels  $\leq 5$  years during the core phase 3 ASCLEPIOS I/II (NCT02792218/NCT02792231) and on-going open-label ALITHIOS (NCT03650114) extension studies.

### Background:

Cumulative safety data from core phase 3 clinical trials and ALITHIOS extension study have shown that most patients with relapsing multiple sclerosis treated with ofatumumab  $\leq 4$  years had serum IgG and IgM levels that remained above lower limit of normal (LLN).

### Design/Methods:

Change in IgG/IgM levels from baseline for up to 5 years of ofatumumab treatment was analyzed in the overall (N=1969), continuous (ofatumumab in core+extension; N=1292), and switch (teriflunomide in core, ofatumumab in extension; N=677) groups. Proportion of patients with IgG/IgM levels  $<LLN$  and the number of patients with serious infections within 1 month before/after IgG/IgM  $<LLN$  were analyzed.

### Results:

In the overall group, IgG levels did not drop below LLN in 98% of patients at any assessment from the first dose of ofatumumab for  $\leq 5$  years. Mean IgG levels remained stable for  $\leq 5$  years (mean % change from baseline to Week 264, -2%). Serious infections were reported in 7.5% of patients with IgG levels  $<LLN$ . IgM levels did not drop below LLN at any assessment in 69.4% of patients. Although mean IgM levels decreased, they remained above LLN (mean % change from baseline to Week 264, -49%). 1.7% of patients with IgM levels  $<LLN$  had serious infections. Treatment

interruptions/discontinuations were reported in 0.2%/0.2% and 10.3%/3.6% patients due to low IgG and IgM, respectively. Sensitivity analyses demonstrated that interruptions/ discontinuations did not affect the overall IgG/IgM pattern.

### Conclusions:

With  $\leq 5$  years of ofatumumab treatment, the majority of patients did not have Ig levels that dropped below the LLN at any assessment. Overall, the number of serious infections was low in patients with Ig levels that dropped below the LLN.

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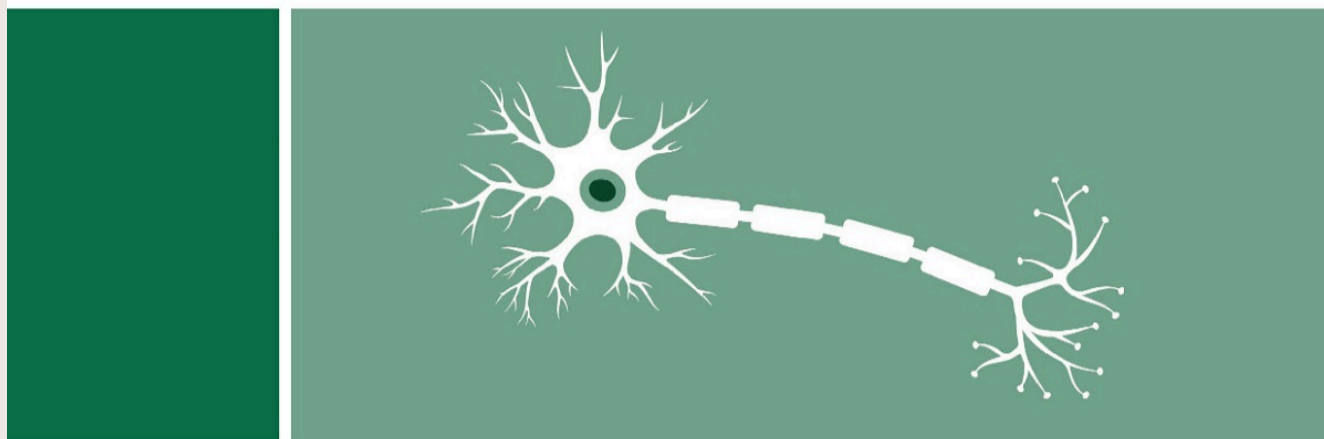
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