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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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Abstract Text:

Background:

Ofatumumab, the first fully human anti-CD20 monoclonal antibody, demonstrated superior efficacy versus teriflunomide in relapsing multiple sclerosis (RMS) patients in the Phase 3 ASCLEPIOS I/II trials. A decline in serum immunoglobulin (Ig) levels was observed with other anti-CD20 therapies.

Objectives:

To determine serum IgG and IgM levels and investigate associations between IgG/IgM levels and risk of infections in ofatumumab-treated patients.

Methods:

In the ASCLEPIOS trials, patients received subcutaneous ofatumumab 20 mg on Days 1, 7, and 14, Week 4, and every 4 weeks thereafter or once-daily oral teriflunomide 14 mg for up to 30 months (average follow-up duration: 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). A notable decline in IgG/IgM levels was defined as 50% of the lower limit of normal (LLN) at any time (IgG, 3.5 g/L; IgM, 0.2 g/L). Outcomes included the proportion of patients with IgG/IgM levels <50% LLN, and association between low IgG/IgM levels and incidence of infections.

Results:

At Week 120, no patients reached IgG levels <50% LLN with ofatumumab (median IgG [g/L]: ASCLEPIOS I and II, 10.57 and 9.57, respectively) or teriflunomide (10.01 and 9.65). The proportion of patients who reached IgM levels <50% LLN was 2.1% (n=20/944) with ofatumumab (median IgM [g/L]: 0.91 and 0.59) and 0.6% (n=6/933) with teriflunomide (0.84 and 0.92) at Week 120. Of these patients, five experienced infections with ofatumumab, mostly non-serious (Grade 1/2 in severity), except one Grade 3 recurrent urinary tract infection, but all infections were resolved. One patient on teriflunomide who experienced nasopharyngitis had not recovered at the time of last follow-up.

Conclusions:

A reduction in serum IgG levels <50% LLN was not observed with either treatment. IgM levels showed reductions with both ofatumumab and teriflunomide treatments; there was no apparent association with increased rate of serious/non-serious infections in RMS patients.

Title:
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Category:
Disease-modifying therapy

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No

Late Breaking Reason:

Data was not available at the time of regular submission

Category: Disease-modifying therapy
Keywords:
Disease-modifying treatments in MS, Immunology and MS and Safety of DMTs in MS

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