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Early Effect of Ofatumumab on B-Cell Counts and MRI Activity in Relapsing Multiple Sclerosis Patients: Results from the Aplios Study

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Abstract Text:

Background:

B cells play a major role in the pathogenesis of multiple sclerosis (MS). Ofatumumab, the first fully human anti-CD20 monoclonal antibody, with a monthly 20 mg subcutaneous (s.c) dosing regimen suppressed 94–98% of the gadolinium-enhancing (Gd+) lesions versus teriflunomide in the Phase 3 ASCLEPIOS I/II relapsing multiple sclerosis (RMS) trials. In APLIOS, the onset of ofatumumab effect on B-cell depletion and MRI activity can be determined.

Objectives:

To evaluate the onset of ofatumumab 20 mg s.c. effect on B-cell depletion and suppression of Magnetic Resonance Imaging activity in RMS patients.

Methods:

APLIOS was a 12-week, open-label, Phase 2, bioequivalence study in RMS patients (N=284) who received ofatumumab 20 mg (0.4 mL) s.c. loading doses on Days 1, 7, and 14, and maintenance doses every 4 weeks from Week 4 via an autoinjector pen (SensoReady) or a prefilled syringe. Suppression of CD19+ B cells was measured 9 times over 12 weeks. Gd+ lesion counts were assessed at baseline and at Weeks 4, 8, and 12.

Results:

Ofatumumab rapidly depleted circulating B cells, from a median B-cell count of 219 cells/μL (Day 1) to 10 cells/μL (Day 4) and 1 cell/μL by the end of the loading regimen (Week 4). The proportion of patients with B-cell counts of <10 cells/μL was >65% after the first injection by Day 7, 94% by Week 4, and sustained >95% at all following injections. Ofatumumab treatment reduced the mean number of Gd+ lesions from 1.5 (baseline) to 0.8, 0.3, and 0.1 by Weeks 4, 8, and 12, respectively; the proportion of patients free from Gd+ lesions at the corresponding time points were 66.5%, 86.7%, and 94.1%.

Conclusions:

Ofatumumab 20 mg s.c. monthly dosing regimen resulted in a rapid, close-to-complete and sustained B-cell depletion over 12 weeks, leading to a profound reduction of Gd+ lesions in RMS patients, consistent with the effects observed in the pooled Phase 3 ASCLEPIOS I/II patient population.

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