#0892: 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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Type

Abstract

Topic

MS and related disorders

Category

Oral

Background and aims

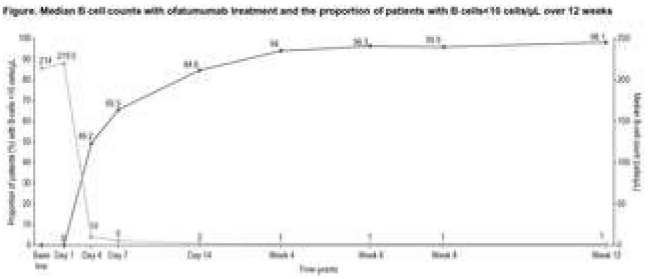
Ofatumumab, the first fully human anti-CD20 monoclonal antibody with a monthly 20 mg subcutaneous (s.c.) dosing regimen, of gadolinium-enhancing (Gd+) lesions versus teriflunomide in the Phase 3 ASCLEPIOS I/II relapsing multiple sclerosis (RMS) trials. We evaluated the onset of ofatumumab effect on B-cell depletion and magnetic resonance imaging activity in RMS patients in APLIOS.

Methods

APLIOS was a 12-week, open-label, Phase 2 bioequivalence study in 284 patients who received ofatumumab 20 mg (0.4 mL) s.c. loading doses on Days 1, 7 and 14, and a maintenance dose every 4 weeks (starting at Week 4) via an autoinjector pen (SensoReady) or a prefilled syringe. Suppression of CD19+ B cells and Gd+ lesions was serially assessed over 12 weeks.

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 over 12 weeks is presented in Figure. Ofatumumab 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 proportions of patients free from Gd+ lesions at the corresponding time points were 66.5%, 86.7% and 94.1%.



Median B cell counts with ofatumumab treatment and the proportion of patients with B cells<10 cells/μL over 12 weeks

Conclusion

Ofatumumab treatment 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 population.

Disclosure

This study was funded by Novartis Pharma AG, Basel, Switzerland. A detailed disclosure from each author will be included in the oral/poster presentation. Abstract also submitted to AAN 2020; acceptance pending.

Affirmations

Authors agreement: I confirm, that all authors mentioned in the author block of this abstract have been informed about, and agreed to this submission. (I confirm)

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