#0792: Effect of Ofatumumab on B-cell Depletion and Efficacy Outcomes: Subgroup Analysis from the Pooled Phase 3 ASCLEPIOS I and II Trials

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Type

Abstract

Topic

MS and related disorders

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Background and aims

Ofatumumab, the first fully human anti-CD20 monoclonal antibody with a monthly 20 mg subcutaneous (s.c.) dosing regimen, demonstrated superior efficacy versus teriflunomide in the Phase 3 ASCLEPIOS I/II relapsing multiple sclerosis trials. We evaluated the effect of ofatumumab on B-cell depletion and efficacy outcomes in subgroups of patients defined by baseline characteristics.

Methods

In the ASCLEPIOS I/II trials, patients were randomised to receive s.c. ofatumumab 20 mg (loading dose: Days 1, 7, and 14; maintenance dose: every 4 weeks from Week 4) or oral teriflunomide 14 mg once-daily, for up to 30 months. B-cell numbers were determined at baseline and over the course of 96 weeks in all patients and in subgroups by quartiles of baseline body weight (kg): Q1 (<60.1), Q2 (>=60.1–<70.8), Q3 (>=70.8–<84.4), and Q4 (>=84.4). Annualised relapse rate (ARR) and 3-month/6-month confirmed disability worsening (3mCDW/6mCDW) were compared in different subgroups defined by demographics/baseline characteristics.

Results

In both the total population and across body weight subgroups, >90% of ofatumumab-treated patients achieved B-cell counts <=40 cells/µL at Week 2, >97% at Week 4, and 96%–100% over the 96 weeks. Reductions in ARR, 3mCDW and 6mCDW favoured ofatumumab versus teriflunomide across all subgroups. Similar efficacy was achieved between all subgroups; detailed data will be presented at the meeting.

Conclusion

The selected ofatumumab dosing regimen achieved rapid B-cell depletion in all patients, regardless of body weight. Furthermore, ofatumumab demonstrated similar treatment benefits across different subgroups (including body weight) consistent with the effects observed in the overall pooled 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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