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Title
Effect of Longer-term Ofatumumab Treatment on Disability Progression and Brain Volume Change

Introduction
In the ASCLEPIOS I/II core studies, ofatumumab delayed disability accrual compared with teriflunomide. Progression independent of relapse activity (PIRA) was the main contributor to overall 3-/6-month confirmed disability worsening (3/6mCDW). We assessed CDW, PIRA, relapse-associated worsening (RAW), and brain volume change (BVC) in relapsing multiple sclerosis patients receiving ofatumumab for up to 5 years.

Methods
Results are presented in this abstract for up to 4 years (ASCLEPIOS + ALITHIOS open-label extension) in patients on continuous ofatumumab and those switched from teriflunomide in the extension (full analysis set); 5-year data will be available at congress. CDW, PIRA (CDW events without prior confirmed relapses), RAW (event onset <90 days from a relapse), percent BVC (PBVC) and annualized rates of BVC (ABVC) were assessed.

Results
Of 1882 patients randomised in ASCLEPIOS I/II, 1367 entered ALITHIOS (Figure 1). Most patients were free from 3/6mCDW events. Up to 4 years (cut off:25-Sep-2021) 12.6% and 15.9% patients had 6mCDW in the continuous and switch groups, respectively. In the continuous group, the 6mPIRA Kaplan-Meier cumulative event rate (KM-CER) remained low (11.0%) and 6mPIRA accounted for 72.3% patients with 6mCDW; 6mRAW (KM-CER: 3.5%) accounted for only 25.2% patients (Table 1). At week 240, overall mean PBVC remained low (continuous/switch: −1.42%/−1.62%). ABVC for continuous ofatumumab also remained low(core:−0.34%/year; extension:−0.28%/year). In the switch group, ABVC was −0.42%/year(core) and −0.29%/year(extension).

Conclusion
With longer-term ofatumumab treatment, disability worsening was predominantly PIRA, the annual rate of BVC remained low, and most patients remained free from disease progression. Outcomes favoured early initiation with ofatumumab.

Disclosure
The study was supported by Novartis Pharma AG, Switzerland. The detailed author disclosures will be provided in the subsequent presentation.

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