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Body

Title
Five-Year Efficacy Outcomes of Ofatumumab in Relapsing MS Patients: Insights From ALITHIOS Open-label Extension Study

Introduction
In the Phase 3 ASCLEPIOS I/II trials, ofatumumab reduced clinical and MRI disease activity versus teriflunomide in relapsing multiple sclerosis (RMS) patients; sustained reductions were observed with extended treatment (up to 4 years) in the ongoing, open-label ALITHIOS extension study. Here, we report ofatumumab efficacy outcomes for up to 5 years.

Methods
This analysis included participants randomised to ofatumumab/teriflunomide in the ASCLEPIOS I/II trials (core study) and who received ofatumumab in ALITHIOS extension study (data cut-off: 25-Sep-2022). Endpoints analysed by year included annualized relapse rates (ARR), MRI lesion activity (Gd+T1 and new/enlarging T2 lesions) and NEDA-3 for up to 5 years in the continuous (ofatumumab [core+extension]; N=690) and switch (teriflunomide [core]/ofatumumab [extension]; N=677) groups.

Results
Patients in the continuous group maintained a low ARR over Years 1–5; while in the switch group, a marked reduction was observed from Year 2–3 (0.15–0.07) and maintained through Years 3–5 (0.05). Profound suppression of MRI lesion activity was maintained in the continuous group up to Year 5; while in the switch group, suppression was observed from Year 3–5. In the continuous group, the odds of achieving NEDA-3 increased from Year 2 (80%) and reached maximum at Year 5 (93.4%) (Figures 1-3).

Conclusion
Continuous ofatumumab showed sustained efficacy on relapses and an almost complete suppression of MRI lesion activity for up to 5 years. Teriflunomide-to-ofatumumab switch resulted in pronounced reductions in these outcomes through Years 3–5. Ofatumumab treatment showed higher odds of achieving NEDA-3 over time in both groups.

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

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ARR.png	Annualized relapse rate (ARR)...	No section selected	Preview	Download
NEDA-3.png	NEDA-3 status in ASCLEPIOS...	No section selected	Preview	Download
MRI lesion activity.png	MRI lesion activity in ASCLEPI...	No section selected	Preview	Download