

Longer-term (up to 6 Years) Efficacy of Ofatumumab in Recently Diagnosed Treatment-Naive Relapsing Multiple Sclerosis

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INTRODUCTION

Ofatumumab demonstrated superior efficacy and similar safety versus teriflunomide in the Phase 3 ASCLEPIOS I/II overall relapsing multiple sclerosis (RMS) population and in recently diagnosed treatment-naive (RDTN) participants (diagnosed ≤ 3 years). Data from ALITHIOS (open-label extension study) previously demonstrated sustained efficacy for up to 5 and 4 years in the overall and RDTN subgroups, respectively. Here, ofatumumab's efficacy in RDTN participants up to 5 years is reported, with 6-year data to be presented at Congress.

DESIGN/METHODS

These analyses (data cut-off: 25-Sep-2022 [up to 5 years]/25-Sep-2023 [up to 6 years]) include cumulative data from RDTN participants originally randomized to ofatumumab (continuous group) and those originally randomized to teriflunomide and switched to ofatumumab in ALITHIOS (switch group).

RESULTS

The RDTN subgroup comprised 314/301 in the continuous/switch groups (mean age at baseline: 36.8/35.7 years; 69.1%/65.8% female; mean EDSS: 2.30/2.28). In the 5-year

analyses, the continuous group sustained a low annualized relapse rate (ARR) over Years 1–5 (0.1–0.01). Marked reductions in ARR in the switch group from Year 2–3 (0.1–0.053) were sustained through Years 3–5 (0.053–0.037). T2 lesion activity was suppressed in the continuous group up to Year 5, and from Year 3–5 in the switch group. The odds of achieving no evidence of disease activity (NEDA-3) in the continuous/switch groups increased from 89%/36% at Year 2 to ≥90% in both groups at Year 5 (Figure 1).

CONCLUSIONS

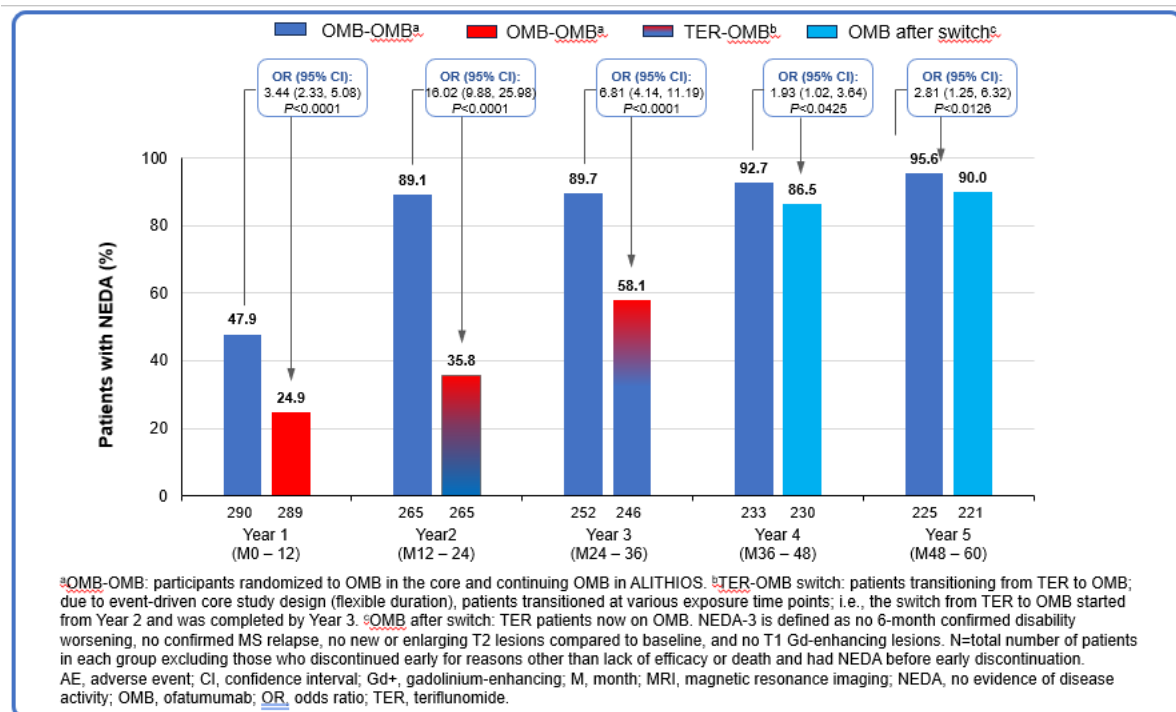
Ofatumumab demonstrates sustained long-term efficacy in people with RDTN RMS, supporting its use early in the disease course.

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DISCLOSURES:

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

Figure 1: NEDA-3 status up to 5 Years of Ofatumumab Treatment



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