Longer-Term Safety and Efficacy of Ofatumumab in People With Relapsing Multiple Sclerosis for Up to 6 Years

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INTRODUCTION

Ofatumumab demonstrated superior efficacy and favourable safety versus teriflunomide in the Phase 3 ASCLEPIOS I/II trials in people with relapsing multiple sclerosis (pwRMS). Previously reported data showed sustained efficacy and a favourable safety profile of ofatumumab in pwRMS up to 5 years. Here, we aim to present the safety and efficacy of ofatumumab treatment for up to 6 years.

DESIGN/METHODS

Efficacy analyses will include all participants randomised in ASCLEPIOS I/II and their data from first dose in ASCLEPIOS I/II, whereas safety analyses will include all participants who received at least one dose of ofatumumab in either ASCLEPIOS I/II, APOLITOS, APLIOS or ALITHIOS (cut-off date: 25-Sep-2023). Efficacy will be analysed by randomised treatment in the core study, with those randomised to ofatumumab referred to as continuous group and to teriflunomide as switch group.

RESULTS

Previously reported 5-year data (cut-off: 25-Sep-2022) showed a sustained low annualised relapse rate (ARR) and almost complete suppression of MRI lesion activity in the continuous group. In the switch group, ARR was markedly reduced from Year 2–3 (0.16–0.06) and remained low through Years 3–5 (0.05), and MRI lesion activity was almost completely suppressed through Years 3–5. At Year 5, 90% of patients reached NEDA-3 in both groups. The safety profile of ofatumumab remained consistent with no new safety signals over 5 years. Updated 6-year efficacy and safety results will be presented at the congress.

CONCLUSIONS

These analyses will help inform physicians on the longer-term safety and efficacy profile of ofatumumab in pwRMS.

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DISCLOSURES:

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