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### Longer-Term Safety and Efficacy of Ofatumumab in People with Relapsing Multiple Sclerosis for up to 6 Years

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#### Abstract Text:

**Background:** Ofatumumab, a fully human anti-CD20 monoclonal antibody, demonstrated superior efficacy vs teriflunomide in the phase 3 ASCLEPIOS I/II trials in people with relapsing multiple sclerosis (pwRMS). Previously reported data for up to 5 years demonstrated sustained efficacy and a favorable safety profile in pwRMS.

**Objectives:** To assess ofatumumab's longer-term safety and efficacy for up to 6 years in pwRMS.

**Methods:** Efficacy analyses will include all participants randomized in ASCLEPIOS I/II and their data from the first dose in ASCLEPIOS I/II, whereas safety analyses will include all participants who received at least 1 dose of ofatumumab in ASCLEPIOS I/II, APOLITOS, APLIOS, or ALITHIOS (cutoff: Sep 25, 2023). Efficacy will be analyzed by the randomized treatment in the core study, with those randomized to ofatumumab being referred to as the continuous group and those randomized to teriflunomide as the switch group.

**Results:** Mean baseline age in ASCLEPIOS I/II (N=1882) was ~38 years, ~67.6% were female, and mean Expanded Disability Status Scale score was ~2.9 in both groups. Previously reported 5-year data (cutoff: Sep 25, 2022) for ofatumumab showed a sustained, low annualized relapse rate (ARR) and sustained and almost complete suppression of magnetic resonance imaging (MRI) lesion activity in the continuous group. In the switch group, ARR was markedly reduced from Years 2-3 (0.16-0.06) and remained low through Years 3-5 (0.05). MRI lesion activity was almost completely suppressed through Years 3-5. At Year 5, 9/10 patients reached no evidence of disease activity in both groups. Exposure-adjusted incidence rate of adverse events (AEs), serious AEs, serious infections, and malignancies remained consistent, with no increased risk over 5 years. Mean immunoglobulin (Ig) G levels remained stable (above the lower limit of normal [LLN]: 5.65 g/L), whereas mean IgM levels decreased but remained above the LLN (0.4 g/L). 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.

**Title:**

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

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**Preferred Presentation Format:**

Poster

**Category:**

Disease-modifying therapy

**Has this abstract been presented/published elsewhere prior to this meeting?:**

No

**Have you simultaneously submitted this abstract to another organization for consideration?:**

Yes

**Simultaneous submission details:**

The abstract was originally submitted to The American Academy of Neurology (AAN) 2024 for consideration. AAN 2024 will be held April 13-18, 2024. Additionally, please note, as it currently stands and as of the CMSC submission deadline, the abstract is awaiting the outcome notification status.

**Would you give CMSC and International Journal of MS Care the first preference to any article that is submitted for publication based on this abstract presentation?:**

No

**Category:** Disease-modifying therapy

**Keywords:**

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**Any relevant financial relationships?** Yes

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Alexion	Contracted Research and Scientific Advisory Boards; Speaker honoraria and travel support
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