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**Ofatumumab Reduces Clinical and Radiological Activity in People with Recently Diagnosed Treatment-Naive Relapsing Multiple Sclerosis Irrespective of Baseline Serum Neurofilament Light Chain Levels**

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**Abstract:**

**Background:** Data from the Phase 3 ASCLEPIOS I/II trials (ofatumumab vs teriflunomide in people with relapsing multiple sclerosis [pwRMS]) demonstrated that baseline serum neurofilament light chain (sNfL) levels were prognostic for on-study lesion formation in the overall population, including a subgroup of recently diagnosed (within 3 years) treatment-naive (RDTN) participants.

**Objectives:** To compare the efficacy of ofatumumab versus teriflunomide in reducing relapses and new/enlarging T2 (neT2) lesions in RDTN participants based on their baseline sNfL levels.

**Methods:** A baseline sNfL cut-off was predefined by the median sNfL value for the overall population across the ASCLEPIOS I/II trials; RDTN participants were stratified into high ( $\geq$ median [9.3 pg/mL]) and low ( $<$ 9.3 pg/mL) sNfL categories. Adjusted annualized relapse rates (ARR) and annualized neT2 lesion rates were assessed with ofatumumab versus teriflunomide in each sNfL category over the study duration (up to 30 months). The effect of treatment on the proportion of participants achieving no evidence of disease activity (NEDA-3) at Month 12 and 24 was also compared within each sNfL category.

**Results:** Across 576 RDTN participants with baseline sNfL available, ARR were reduced by 63.4% ( $p=0.002$ ) and 37.2% ( $p=0.119$ ) in the high and low sNfL categories, respectively, with ofatumumab versus teriflunomide. Ofatumumab reduced the annualized rate of neT2 lesions by 85.5% and 85.8% versus teriflunomide for high and low sNfL categories, respectively (both  $p<0.001$ ). A higher proportion of participants achieved NEDA-3 status with ofatumumab versus teriflunomide treatment, regardless of baseline sNfL levels ( $p<0.001$  in both sNfL groups at all timepoints).

**Conclusions:** Ofatumumab was consistently associated with reductions in clinical and radiological activity versus teriflunomide in RDTN participants regardless of their baseline sNfL levels. The results support the benefit of using high-efficacy therapies, such as ofatumumab, at an early stage in the MS disease course irrespective of sNfL levels.

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