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B-Cell Depletion and Efficacy Outcomes of Ofatumumab Are Consistent across Different Body Mass Index Categories: Insights from the Asclepios I/II Trials

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Abstract Text:
Background: In the ASCLEPIOS I/II trials, ofatumumab demonstrated superior efficacy and a favorable safety profile over teriflunomide in people with relapsing multiple sclerosis (pwRMS), with consistent results across different subgroups. Body mass index (BMI) can be a possible confounding factor affecting multiple sclerosis disease activity.

Objectives: To evaluate the effect of ofatumumab on B-cell depletion and efficacy outcomes in the subgroup of patients from the ASCLEPIOS I/II trials defined by their baseline BMI.

Methods: Patients received ofatumumab 20 mg or teriflunomide 14 mg for up to 30 months. Median B-cell counts and proportion of patients with low B-cell counts (≤10 cells/μL) over 96 weeks were assessed among patients categorized by typical BMI cutoffs (kg/m^2) (<18.5 [n=76], ≥18.5 to <25.0 [n=921], ≥25 to <30 [n=511], and ≥30.0 [n=372]) and baseline BMI quartiles (kg/m^2) (Q1, <21.5; Q2, ≥21.5 to <24.6; Q3, ≥24.6 to <28.7; and Q4, ≥28.7 [n=470 each]). Impact of different BMI categories on annualized relapse rate (ARR), time to 3-/6-month confirmed disability worsening (3/6mCDW), number of gadolinium-enhancing (Gd+) T1 lesions, and annualized rate of new/enlarging T2 lesions (neT2) were assessed.

Results: Across all BMI categories, median B-cell counts reduced rapidly with ofatumumab by Week (W)2 (≤10 cells/μL) and sustained at 0 cells/μL up to W96, whereas with teriflunomide, B-cell counts ranged between 115 and 190 cells/μL throughout the observation period. Approximately >75% of ofatumumab-treated patients achieved B-cell counts ≤10 cells/μL at W2; ≥90% achieved B-cell counts ≤10 cells/μL at W4, and these were maintained over the 96 weeks regardless of BMI. Reductions in ARR, 3mCDW, 6mCDW, Gd+ T1, and neT2 lesions favored ofatumumab vs teriflunomide across all BMI categories.

Conclusions: Monthly 20-mg subcutaneous administration of ofatumumab showed a high degree of efficacy across pwRMS, independent of BMI, allowing for ease of use with no need for dose adjustment. The approved dose and more frequent subcutaneous administration of ofatumumab seems to cover the full spectrum of BMI in pwRMS.

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B-Cell Depletion and Efficacy Outcomes of Ofatumumab Are Consistent across Different Body Mass Index Categories: Insights from the Asclepios I/II Trials

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