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**B-Cell Depletion and Efficacy Outcomes of Ofatumumab Are Consistent Across Different Body Mass Index Categories: Insights From ASCLEPIOS I and II Trials**

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**Abstract:**

**Background:** In 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 (MS) disease activity.

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

**Methods:** Patients received either ofatumumab 20mg or teriflunomide 14mg for up to 30 months. Median B-cell counts and proportion of patients with low B-cell counts ( $\leq 10$  cells/ $\mu\text{L}$ ) over 96 weeks were assessed among patients categorized by typical BMI cutoffs ( $\text{kg}/\text{m}^2$ ) ( $< 18.5$  [n=76];  $\geq 18.5$ - $< 25.0$  [n=921];  $\geq 25$ - $< 30$  [n=511]; and  $\geq 30.0$  [n=372]) and baseline BMI quartiles ( $\text{kg}/\text{m}^2$ ) (Q1:  $< 21.5$ ; Q2:  $\geq 21.5$ - $< 24.6$ ; Q3:  $\geq 24.6$ - $< 28.7$ ; Q4:  $\geq 28.7$  [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 ( $\leq 10$  cells/ $\mu\text{L}$ ) and sustained at 0 cells/ $\mu\text{L}$  up to W96, whereas with teriflunomide, B-cell counts ranged between 115 and 190 cells/ $\mu\text{L}$  throughout the observation period. About  $> 75\%$  of ofatumumab-treated patients achieved B-cell counts  $\leq 10$  cells/ $\mu\text{L}$  at W2;  $\geq 90\%$  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 versus teriflunomide across all BMI categories.

**Conclusions:** Monthly 20mg 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 every 4 weeks subcutaneous administration of ofatumumab seems to cover the full spectrum of BMI in pwRMS.

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