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Ofatumumab Vs Teriflunomide in Relapsing Multiple Sclerosis: Analysis of No Evidence of Disease Activity (NEDA-3) from the Asclepios I and II Trials

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Abstract Text:

Background:

Ofatumumab, the first fully human anti-CD20 monoclonal antibody, demonstrated superior efficacy versus teriflunomide in the Phase 3 ASCLEPIOS I/II relapsing multiple sclerosis (RMS) trials. No evidence of disease activity (NEDA-3), a comprehensive composite measure, is commonly used to determine the treatment outcome in RMS.

Objectives:

To investigate the effect of subcutaneous ofatumumab 20 mg (monthly) versus oral teriflunomide 14 mg (once daily) in achieving NEDA-3, and to separately assess the annualized relapse rate (ARR) and gadolinium-enhancing (Gd+) T1 lesions activity in the pooled ASCLEPIOS I/II trials.

Methods:

We pooled data from the ASCLEPIOS I (n=927) and II (n=955) trials. Outcomes included NEDA-3 (defined as a composite of no 6-month confirmed disability worsening [6mCDW], no confirmed multiple sclerosis relapse, no new/enlarging T2 lesions, and no Gd+ T1 lesions) and its individual components in a modified full analysis set (modified FAS; logistic regression model). ARR by time intervals and Gd+ T1 lesions in the FAS (negative binomial model for both) were also analyzed.

Results:

The odds of achieving NEDA-3 with ofatumumab versus teriflunomide were >3-fold higher at Month (M) 0–12 (47.0% vs 24.5% of patients; odds ratio [95% confidence interval (CI)]: 3.36 [2.67; 4.21], p<0.001) and >8-fold higher at M12–24 (87.8% vs 48.2% of patients; 8.09 [6.26; 10.45], p<0.001). Over 2 years, a higher proportion of ofatumumab-treated patients were free from 6mCDW (91.9% vs 88.9%), relapses (82.3% vs 69.2%) and lesion activity (54.1% vs 27.5%) compared with teriflunomide. Ofatumumab significantly reduced ARR compared with teriflunomide at all cumulative time intervals: M0–3 (p=0.011), and all subsequent time intervals from M0–27 (p<0.001). Ofatumumab significantly reduced the mean number of Gd+ T1 lesions per scan by 95.9% compared with teriflunomide (mean [95% CI]: 0.02 [0.01; 0.03] vs 0.50 [0.42; 0.59]; p<0.001).

Conclusions:

Ofatumumab increased the probability of achieving NEDA-3 and demonstrated superior efficacy versus teriflunomide in patients with RMS.

Title:

Ofatumumab Vs Teriflunomide in Relapsing Multiple Sclerosis: Analysis of No Evidence of Disease Activity (NEDA-3) from the Asclepius I and II Trials

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