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

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INTRODUCTION

Ofatumumab, the first fully human anti-CD20 monoclonal antibody, demonstrated superior efficacy over teriflunomide in the Phase 3 ASCLEPIOS I/II relapsing multiple sclerosis (RMS) trials. We evaluated the effect of subcutaneous ofatumumab 20 mg (monthly) versus oral teriflunomide 14 mg (once daily) in achieving no evidence of disease activity (NEDA-3) and separately assessed the annualised relapse rate (ARR) and gadolinium-enhancing (Gd+) T1 lesions from the ASCLEPIOS I/II trials.

METHODS

Data were pooled from ASCLEPIOS I (n=927) and II (n=955) trials. Outcomes included NEDA-3 (defined as composite of absence of 6-month confirmed disability worsening [6mCDW], confirmed MS relapse, new/enlarging T2 lesions and Gd+ T1 lesions) and its individual components (logistic regression model), ARR by time-interval and Gd+ T1 lesions (negative binomial model for both).

RESULTS

The odds of achieving NEDA-3 with ofatumumab versus teriflunomide was >3-fold higher at Month (M) 0–12 (47.0% vs 24.5% patients; odds ratio [95% confidence interval (CI)]: 3.36

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[2.67–4.21], p<0.001) and >8-fold higher at M12–24 (87.8% vs 48.2% patients; 8.09 [6.26–10.45], p<0.001). Over 2 years, a higher proportion of ofatumumab- than teriflunomide-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%). Ofatumumab significantly reduced ARR versus teriflunomide at all cumulative time-intervals: M0–3 (p=0.011) and subsequent M0–27 (p<0.001). Ofatumumab significantly reduced the number of Gd+T1 lesions per scan by 95.9% versus 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 RMS patients.

Disclosure:

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