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Efficacy and Safety of Ofatumumab Versus Teriflunomide in Patients with Relapsing Multiple Sclerosis: Phase 3 Asclepios I and II Trials

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Abstract Text:

Background:

Ofatumumab is the first fully human anti-CD20 monoclonal antibody, administered with a monthly 20 mg subcutaneous (s.c.) dosing regimen.

Objectives:

To investigate the efficacy and safety of ofatumumab versus teriflunomide in relapsing multiple sclerosis (RMS) patients.

Methods:

ASCLEPIOS I and II were two identical Phase 3, double-blind, double-dummy, active comparator-controlled, parallel-group, innovative, adaptive-design (with flexible duration), multicentre trials in patients aged 18–55 years with an Expanded Disability Status Scale score of 0–5.5 at screening. Patients were randomized (1:1) to receive s.c. ofatumumab 20 mg (loading dose: Days 1, 7, and 14; maintenance dose: every 4 weeks from Week 4) or oral teriflunomide 14 mg once daily, for up to 30 months. The primary endpoint was annualized relapse rate (ARR). Key secondary endpoints included 3- and 6-month confirmed disability worsening (3mCDW/6mCDW), 6-month confirmed disability improvement (6mCDI), magnetic resonance imaging-related outcomes, and serum neurofilament light chain (NfL) levels. Safety and tolerability was also assessed.

Results:

Of 1882 enrolled patients (ASCLEPIOS I/II: N=927/955), 1578 completed the core study. Ofatumumab reduced ARR (ASCLEPIOS I and II: 50.5% and 58.5%), gadolinium-enhancing T1 lesions (97.5% and 93.8%), and new/enlarging T2 lesions (82.0% and 84.5%) versus teriflunomide (all, $p<0.001$). In the pre-specified ASCLEPIOS I/II pooled analysis, ofatumumab reduced the risk of 3mCDW by 34.4% ($p=0.002$) and 6mCDW by 32.5% ($p=0.012$), and numerically increased the probability to achieve 6mCDI by 35.2% ($p=0.094$), versus teriflunomide. Ofatumumab reduced serum NfL levels versus teriflunomide in the first measurement at Month 3 (ASCLEPIOS I, $p=0.011$; ASCLEPIOS II, $p<0.001$) and in all subsequent assessments (all, $p<0.001$). No difference in the slope of brain volume change from baseline was observed between treatments ($p=0.116$ [ASCLEPIOS I] and 0.129 [ASCLEPIOS II] versus teriflunomide). Adverse events occurred in 83.6% and 84.2% of patients receiving ofatumumab and teriflunomide, respectively. Systemic injection-related reactions occurred in 20.6% and 15.3% of ofatumumab and teriflunomide-treated

patients, respectively. Rates of serious infections (ofatumumab, 2.5%; teriflunomide, 1.8%) and malignancies (0.5% and 0.3%, respectively) were low.

Conclusions:

Ofatumumab demonstrated superior efficacy versus teriflunomide, with an acceptable safety profile, in patients with RMS.

Title:
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