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# Baseline Characteristics of Patients with Relapsing Multiple Sclerosis in ASCLEPIOS Phase 3 Trials of Ofatumumab Versus Teriflunomide (P3.2-096)

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### **Abstract**

**Objective:** To present the baseline characteristics of patients enrolled in the ASCLEPIOS I and II trials.

**Background:** ASCLEPIOS I and II are two Phase 3 trials of identical design that are being conducted simultaneously to evaluate the efficacy and safety of ofatumumab versus teriflunomide in patients with relapsing multiple sclerosis (RMS).

Design/Methods: ASCLEPIOS I and II are randomized, double-blind, double-dummy, active comparator-ann.com [https://www.aan.com] randomized II are randomized, double-blind, double-dummy, active comparator-controlled, parallel-group, multicenter trials in RMS patients aged 18–55 years with an Expanded Disability Status Scale (EDSS) score of 0 to 5.5 at screening. Patients were randomized (1:1) to receive either of atumumab 20 mg subcutaneous (s.c.) injections every 4 weeks (following an initial loading regimen of three 20 mg s.c. doses per week in the first 14 days) or teriflunomide 14 mg orally once daily. The primary endpoint is the annualized rate of confirmed relapses. Key secondary endpoints include 3- and 6-month confirmed disability worsening and magnetic resonance imaging (MRI)-related outcomes. The innovative, adaptive study design, with study termination occurring after reaching a prespecified number of events allows for a flexible trial duration.

**Results:** In total, 1882 patients have been enrolled across 385 centers in 37 countries (ASCLEPIOS I, N=927; ASCLEPIOS II, N=955); the majority are female (>65%), Caucasian (>85%), and more than half (60%) had received prior disease-modifying therapy (DMT). The mean age is 38.4 and 38.1 years, and the mean duration of multiple sclerosis since the first symptom is 8.3 and 8.2 years, respectively. In each trial, the mean EDSS score is 2.9 and approximately 40% of patients showed gadolinium-enhancing lesions on brain MRI at screening.

**Conclusions:** The trials have successfully completed patient recruitment. Baseline characteristics of enrolled patients are consistent with a typical RMS population and broadly comparable with other registration trials in RMS, with a relatively high proportion of patients being previously exposed to one or more DMTs.

Disclosure: Dr. Kappos' institution has received compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Actelion, Alkermes, Almirall, Bayer, Biogen, Celgene/Receptos, df-mp, Excemed, GeNeuro SA, Genzyme, Japan Tobacco, Merck, Minoryx, Mitsubishi Pharma, Novartis, Roche, Sanofi-Aventis, Santhera, Teva and Vianex, and license fees for Neurostatus-UHB products. Dr. Kappos' institution has received research support from Bayer, Biogen, Novartis, the Swiss MS Society, the Swiss National Research Foundation, the European Union, and Roche Research Foundations. Dr. Bar-Or has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Atara Biotherapeutics, Biogen, Celgene/Receptos, Genentech/Roche, GlaxoSmithKline, Medimmune, Merck/EMD Serono, Novartis, Sanofi-Genzyme. Dr. Bar-Or has received research support from Atara Biotherapeutics, Biogen, Celgene/Receptos, Genentech/Roche, GlaxoSmithKline, Medimmune, Merck/EMD Serono, Novartis, Sanofi-Genzyme. Dr. Cohen has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Consulting for Alkermes, Biogen, Convelo, EMD Serono, ERT, Gossamer Bio, Mapi, Novartis, Pendopharm, and ProValuate. Dr. Cohen has received personal compensation in an editorial capacity for Multiple Sclerosis Journal – Experimental, Translational and Clinical. Dr. Cohen has

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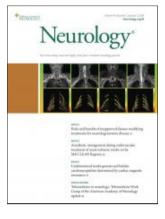
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