Neurology®

April 09, 2019; 92 (15 Supplement) MAY 7, 2019

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

Ludwig Kappos, Amit Bar-Or, Jeffrey Cohen, Giancarlo Comi, Jorge Correale, Patricia K. Coyle, Anne H. Cross, Jerome de Seze, Xavier Montalban, Krzysztof Selmaj, Heinz Wiendl, David Leppert, Cecile Kerloeguen, Roman Willi, Dieter A. Häring, Davorka Tomic, Alexandra Goodyear, Martin Merschhemke, Stephen L. Hauser

First published April 16, 2019,

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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-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 ofatumumab 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

received research support from Genentech, Genzyme, Mallinckrodt, Novartis. Dr. Comi has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Actelion, Bayer, Biogen, Merck Serono, Novartis, Sanofi, Serono Symposia International Foundation, and Teva. Dr. Correale has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Biogen Argentina, Teva Argentina, Novartis Argentina and MERCK Argentina, and Merck/Serono Argentina and Novartis Argentina. Dr. Coyle has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Received consulting fees from Accordant, Acorda, Bayer, Biogen Idec, Celgene, Genentech/Roche, Genzyme/Sanofi, Novartis, Serono and Teva. Dr. Coyle has received research support from Research support from Actelion, Genentech/Roche, MedDay, Novartis and NINDS. Dr. Cross has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Biogen, Celgene, EMD Serono, Genzyme, Genentech, Novartis. Dr. Cross has received research support from Genentech. Dr. De Seze has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Biogen, Sanofi-Genzyme, Teva, Novartis, Roche, Chugai, and Alexion. Dr. De Seze has received research support from Sanofi. Dr. Montalban has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Dr. Montalban received speaking honoraria and travel expenses for scientific meetings, has been a steering committee member of clinical trials or participated in advisory boards of clinical trials in the past 3 years with Biogen, Merck Serono, Genentech, Genzyme, Novartis, Sanofi-Aventis, Teva Pharmaceuticals, Roche, Celgene, Actelion, NMSS and MSIF. Dr. Selmaj has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Celgene, Novartis Pharmaceuticals, Synthon, Merck, Roche, and Biogen. Dr. Selmaj has received research support from Merck.. Dr. Wiendl has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Abbvie, Actelion, Alexion, Biogen, Cognomed, Evgen, F. Hoffmann-La Roche Ltd, MedDay Pharmaceuticals, Merck Serono, Novartis, Roche Pharma AG, Sanofi-Genzyme, and TEVA. Dr. Wiendl has received research support from Biogen, GlaxoSmithKline GmbH, Roche Pharma AG, and Sanofi-Genzyme. Dr. Leppert has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Novartis. Dr. Kerloeguen has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Novartis. Dr. Willi has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Novartis. Dr. Haering has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Novartis Pharma AG. Dr. Tomic has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Employee of Novartis Pharma AG. Dr. Goodyear has nothing to disclose. Dr. Merschhemke has received personal compensation for consulting, serving on a scientific advisory board, speaking, or other activities with Novartis Pharma AG as an employee. Dr. Hauser has received personal compensation for

consulting, serving on a scientific advisory board, speaking, or other activities with Annexon, Symbiotix, Bionure and Neurona; he has also received travel reimbursement from F. Hoffmann-La Roche Ltd and Novartis for CD20-related meetings and presentation.

Disputes & Debates: Rapid online correspondence

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