Long-term Efficacy of Ofatumumab in Patients With Relapsing Multiple Sclerosis

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Objective:

To assess the long-term efficacy of ofatumumab treatment for up to 4 years in patients with relapsing multiple sclerosis (RMS).

Background:

Ofatumumab, a fully human anti-CD20 monoclonal antibody, demonstrated superior efficacy versus teriflunomide in the Phase 3 ASCLEPIOS I/II trials in RMS patients. Evaluation of the long-term efficacy of ofatumumab treatment is important.

Design/Methods:

This analysis (data cut-off: 25-Sep-2021) will include cumulative data from patients randomized to ofatumumab/teriflunomide in the ASCLEPIOS I/II trials (core study) and the ongoing, open-label, ALITHIOS extension study. Patients will be analyzed in two groups: those randomized to ofatumumab in the core (continuous group) and those randomized to teriflunomide in the core with potential switch to ofatumumab in the extension (switch group). Annualized relapse rate (ARR), disability worsening (time-to-3-month/6-month confirmed disability worsening), disability improvement (time-to-6-month confirmed disability improvement), and brain MRI outcomes (number of Gd+T1 lesions and annualized T2 lesion rate) will be assessed.

Results:
Overall, 1882 patients who were randomized in the ASCLEPIOS I/II trials (ofatumumab/teriflunomide: 946/936) will be included. Baseline demographics and disease characteristics have previously been reported for the ASCLEPIOS I/II trials (mean age, ~38 years; female, ~68%, mean EDSS, ~2.9; mean±SD of number of Gd+T1 lesions: ~1.5±3.9; mean volume of T2 lesions, ~13.2 cm^3). Previously reported data showed superiority of ofatumumab versus teriflunomide in reducing ARR, suppressing MRI lesion activity, and delaying disability worsening. In total, 690/946 patients treated with ofatumumab and 677/936 patients treated with teriflunomide entered ALITHIOS. Updated efficacy results for up to 4 years will be presented at the congress.

Conclusions:

These analyses will provide insights on the sustained efficacy of continuous ofatumumab treatment for up to 4 years in patients with RMS, and also on the efficacy of ofatumumab in patients newly switched from teriflunomide.

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