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Compliance and persistence with ofatumumab treatment in patients with relapsing multiple sclerosis in clinical trials for up to 4 years

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Introduction: Ofatumumab (OMB) demonstrated superior efficacy and a similar safety profile to teriflunomide in the ASCLEPIOS I/II trials in relapsing multiple sclerosis (RMS) patients. Sustained efficacy and a consistent safety profile have also been observed in the long term ALITHIOS open-label extension study for up to 4 years. In ASCLEPIOS I/II, 98.8% of patients had ≥80% compliance to the study treatment schedule, and 82.9% randomized to OMB completed the study on drug up to 30 months.
Objectives: To evaluate compliance and persistence with OMB treatment in RMS patients for up to 4 years across the OMB core studies and ALITHIOS extension study.
Methods: Patients completing the core ASCLEPIOS I/II, APOLITOS and APLIOS trials could enter ALITHIOS. Compliance was analyzed for up to 4 years (cut-off: 25-Sep-2021) in overall, continuous (OMB in core) and newly switched (teriflunomide core and OMB extension) groups. Compliance was calculated as the duration of exposure to study drug/duration of on-treatment period×100%, with ≥80% defined as the threshold to indicate patients were compliant. The number of patients continuing OMB (as a measure of treatment persistence) and discontinuing treatment in ALITHIOS, and reasons for discontinuations are also presented.
Results: As of 25-Sep-2021, in the overall (N=1969), continuous (N=1292), and newly switch groups (N=677), 94.9%, 95.1%, and 94.4% of patients were compliant with OMB therapy, respectively. In total, 1715 patients entered the ALITHIOS study; 12 (0.7%) of these were screening failures, and 1703 patients were enrolled in the study and received study treatment; 1508 (87.9%) were ongoing in the study at the time of data cut-off, and 195 (11.4%) discontinued study treatment. The primary reasons for discontinuation in the ALITHIOS study were patient/guardian decision (n=75 [4.4%]); adverse event (n=66 [3.8%]); pregnancy (n=12 [0.7%]); physician decision (n=12 [0.7%]); lack of efficacy (n=12 [0.7%]); lost to follow-up (n=8 [0.5%]); death (n=6 [0.3%]); non-compliance (n=2 [0.1%]); and protocol deviation (n=2 [0.1%]).
Conclusions: Overall ~95% of patients were compliant with OMB treatment across core studies and the open-label extension study, indicating high compliance with monthly subcutaneous OMB therapy. In addition, only a small proportion of RMS patients treated with OMB in the clinical trial setting discontinued treatment, indicating high treatment persistence.
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