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Adherence and Compliance with Subcutaneous Administration of Ofatumumab in Relapsing Multiple Sclerosis

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Abstract Text:

Background: Ofatumumab (OMB), the first fully human anti-CD20 monoclonal antibody, administered with a monthly 20 mg subcutaneous (s.c.) dosing regimen, demonstrated superior efficacy versus teriflunomide (TER) in the two Phase 3 ASCLEPIOS I and ASCLEPIOS II trials in relapsing multiple sclerosis. Patients who completed the double-blind phase of the trials on study drug were eligible for transition to the ongoing open-label extension study ALITHIOS.

Objectives: To evaluate treatment discontinuation and compliance with OMB and TER treatment in the Phase 3 ASCLEPIOS I/II trials and to assess patients' acceptance of transitioning to the ALITHIOS study.

Methods: In ASCLEPIOS I/II, patients were randomized (1:1) to OMB 20 mg s.c. (loading doses, administered at clinic: Days 1, 7, and 14; maintenance doses, administered at home: every 4 weeks from Week 4) or TER 14 mg (orally once daily), for up to 30 study months. Here we report on treatment discontinuation and compliance (defined as exposure to study drug [days]/on-treatment period [days]×100%) in ASCLEPIOS trials and percentage of eligible ASCLEPIOS patients who accepted to transition to the ALITHIOS study and the compliance in this study.

Results: In ASCLEPIOS I, 759/927 (81.9%) randomized patients (OMB: 400/465 [86.0%]; TER: 359/462 [77.7%]) completed the study on study drug. The proportion of patients discontinuing treatment were OMB, 14.0%; TER, 21.2%. The most common reasons for discontinuation (>2% in any group) were patient/guardian decision (OMB: 4.9%; TER: 8.2%), adverse event (OMB: 5.2%; TER: 5.0%), and physician decision (OMB: 2.2%; TER: 6.5%). In ASCLEPIOS II, 753/955 (78.8%) randomized patients (OMB: 383/481 [79.6%]; TER: 370/474 [78.1%]) completed the study on study drug. Proportion of patients discontinuing treatment were OMB, 20%; TER, 21.5%; reasons for discontinuation were patient/guardian decision (OMB: 7.3%; TER: 7.8%), adverse event (OMB: 5.6%; TER: 4.9%) and physician decision (OMB: 5.2%; TER: 6.8%). In both trials compliance was high (>95% of patients falling in the ≥90% compliance category) across treatment groups. Approximately 90% of eligible patients consented to participate in the open-label study; compliance data will be presented.

Conclusions: In ASCLEPIOS trials compliance with home-administered s.c. OMB was high and fewer patients discontinued OMB as compared to TER. The majority of eligible patients accepted transition to the open-label ALITHIOS extension study.

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