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Efficacy of Ofatumumab in Treatment-Naive, First-Switch and Late-Switch Patients: Insights from the Alithios Open-Label Extension Study

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Abstract Text:

Background:

Ofatumumab (OMB), a fully human anti-CD20 monoclonal antibody, reduced annualized relapse rate (ARR), MRI lesion activity, and delayed disability worsening versus teriflunomide (TER) in relapsing multiple sclerosis (RMS) patients who were treatment-naive (TN) or previously treated (PT) with disease-modifying therapies (DMTs) in the Phase 3 ASCLEPIOS I/II trials. All patients entering the ALITHIOS extension study were switched to open-label OMB allowing further insights into OMB efficacy in TN/PT patients and after first and late DMT switch.

Objectives:

To compare clinical and MRI outcomes in patients initiating OMB early versus switching to OMB after one or multiple previous DMTs in the ASCLEPIOS I/II and ALITHIOS studies.

Methods:

Outcomes from ASCLEPIOS I/II (ARR, time-to-6-month confirmed disability worsening [6mCDW], number of Gd+T1 lesions, and annualized T2 lesion rate) for TN and PT patients are presented here. Further analyses to be presented at the congress will compare these outcomes in ASCLEPIOS (up to 30 months treatment) with outcomes over 18 months in ALITHIOS (i.e., post-switch to open-label OMB; data cut-off: 25-Sep-2021) in the following four groups: 1) Early TN: TN patients randomized to OMB in ASCLEPIOS I/II and continued OMB in ALITHIOS; 2) First switch: TN patients randomized to TER in ASCLEPIOS I/II and switched to OMB in ALITHIOS; 3) Late switch: patients PT with ≥ 1 DMTs, randomized to TER in ASCLEPIOS I/II and switched to OMB in ALITHIOS; 4) PT-Longer term: patients who were PT, randomized to OMB in ASCLEPIOS I/II and continued OMB in ALITHIOS.

Results:

In ASCLEPIOS I/II, 1882 patients were randomized and OMB versus TER reduced the ARR by 51% and 53% in the TN (n=749) and PT (n=1133) subgroups, respectively. For 6mCDW, the risk reductions were 36% and 28%; new/enlarging T2 lesions were reduced by 83% and 85%, respectively. Gd+ T1 lesions were reduced by 95% across both subgroups. These findings were in line with the overall ASCLEPIOS I/II population. The analysis from ALITHIOS will be based on the 1367/1882 (72.6%) patients who entered open-label extension study.

Conclusions:

OMB shows consistent efficacy in patients who were TN or switched from other DMTs. Further insights from ALITHIOS on efficacy outcomes following the initiation of OMB early versus first and late switch will be presented at the congress.

Title:

Efficacy of Ofatumumab in Treatment-Naive, First-Switch and Late-Switch Patients: Insights from the Alithios Open-Label Extension Study

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