Abstract 1638

Safety experience with extended exposure to ofatumumab in patients with relapsing multiple sclerosis from Phase 2 and 3 clinical trials

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Background

Ofatumumab, a fully human anti-CD20 monoclonal antibody, demonstrated superior efficacy versus teriflunomide in Phase 3 ASCLEPIOS I/II relapsing multiple sclerosis (RMS) trials. Long-term data to assess the safety and benefit-risk profile of ofatumumab 20 mg per month is required.

Objectives

To report the overall safety data of all patients treated with subcutaneous (s.c.) ofatumumab 20 mg for RMS, including patients who continued treatment and those who were newly switched in the ongoing open-label Phase 3b ALITHIOS study.

Methods

The overall safety population was divided into 2 groups 1) Continuous: Patients randomized to ofatumumab in the core Phase 2 APLIOS (12 weeks) or Phase 3 ASCLEPIOS I/II (up to 30 months) trials and continued in ALITHIOS, or completed core study and continued with the safety follow-up, and 2) Newly-switched: Patients randomized to teriflunomide in ASCLEPIOS I/II and switched to ofatumumab in ALITHIOS. All adverse events (AEs), serious AEs (SAEs) and deaths up to and including the safety cut-off of 100 days after last administration of ofatumumab are included in this safety analysis until 30 November 2019.

Results

A total of 1873 patients (continuous: 1230; newly-switched: 643) were exposed to ofatumumab ([median duration] continuous: 21.0 months; newly-switched: 4.4 months) for 2118.6 patient-years (continuous: 1903 patient-years; newly-switched: 215.6 patient-years). 71.4% of patients (continuous: 82%; newly-switched: 51%) experienced at least one AE; most were mild-to-moderate. AEs led to ofatumumab discontinuation in 3.0% of patients. SAEs were observed in 6.2% of patients. Incidence of infections was 38.5% (continuous: 49.3%, newly-switched: 18.0%). Serious infections occurred in 1.8% of patients. Incidence of injection-related reactions (IRRs) was 23.7% (continuous: 24.9%; newly-switched: 21.3%); most IRRs were non-serious, grade 1 or 2 and none led to ofatumumab discontinuation. Hepatitis B reactivation, progressive multifocal leukoencephalopathy or deaths have not been reported. No cases of opportunistic infections have been identified. Incidence of malignancies was 0.3% (with confounding) and no new cases have been reported in either continuous or newly-switched patients as of the data cut-off time.

Conclusions

No new safety signals were identified in this extended analysis. The safety profile of ofatumumab in RMS patients remains consistent with data reported in the core studies, including the ASCLEPIOS I/II trials.

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