Abstract 1580

Long-term safety, compliance, and effectiveness of ofatumumab in patients with relapsing multiple sclerosis: ALITHIOS Phase 3b study

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Background

Ofatumumab, a fully human anti-CD20 monoclonal antibody, demonstrated superior efficacy versus teriflunomide along with a favorable safety profile in the Phase 3 ASCLEPIOS trials in relapsing multiple sclerosis (RMS) patients. Assessment of the long-term use of subcutaneous (s.c.) ofatumumab 20 mg is important to further understand its benefit-risk profile.

Objectives

To present the design of the ALITHIOS extension study of ofatumumab and evaluate treatment compliance, including treatment discontinuations, in patients transitioning to the ALITHIOS study.

Methods

ALITHIOS is an ongoing Phase 3b, open-label, umbrella extension study which has enrolled eligible patients (approximately 1700 patients) completing the Phase 3 ASCLEPIOS I/II, Phase 2 APOLITOS and APLIOS trials from >300 sites worldwide. ALITHIOS consists of three parts: screening, loading, and open-label treatment. Ofatumumab 20 mg is administered at the site on Day 1 (patients from ASCLEPIOS have a blinded loading part with two additional ofatumumab/matching placebo s.c. injections on Days 7 and 14; no blinding is required for those from the APOLITOS and APLIOS studies) followed by open-label treatment every 4 weeks from Week 4 for up to 5 years. The primary endpoint is the proportion of patients with adverse events (AEs); abnormal laboratory, vital signs or electrocardiogram results; and the proportion of patients meeting predefined criteria of suicidal behavior as per the Columbia Suicide Severity Rating Scale. Secondary endpoints include relapse rate, disability (worsening and improvement), and magnetic resonance imaging outcomes. Patient-reported outcomes was included as an exploratory endpoint. The proportion of eligible patients who accepted transition to ALITHIOS from the Phase 2/3 trials and treatment compliance (defined as exposure to study drug [days]/duration of on-treatment period [days]×100%) are recorded.

Results

As of May 2020, 1692 patients from 37 countries and 294 sites were screened, and 1671 (98.8%) were enrolled into ALITHIOS; 1615 patients are ongoing and 56 (3.3%) patients discontinued. The most common reasons for discontinuation were patient/guardian decision (0.9%), AEs (0.5%), and physician decision (0.2%). The study is expected to complete in 2025. Study design details and compliance data will be presented at the congress.

Conclusions

The ALITHIOS study is designed to allow patients who participated in prior ofatumumab studies to continue with the treatment, and to further assess the benefit-risk profile of ofatumumab in RMS and tolerability in long-term use.

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