Long-term Safety of Ofatumumab in Patients With Relapsing Multiple Sclerosis

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Objective:

To assess the long-term safety and tolerability of ofatumumab treatment in patients with relapsing multiple sclerosis (RMS).

Background:

Ofatumumab, a fully-human anti-CD20 monoclonal antibody with a 20 mg subcutaneous monthly dosing regimen, is approved for treating RMS in adults. Previously published data demonstrated that ofatumumab treatment up to 30 months had a favorable safety profile and was generally well-tolerated. Longer-term safety of ofatumumab in RMS patients continues to be monitored.

Design/Methods:

Patients completing the core ASCLEPIOS I/II, APOLITOS and APLIOS clinical trials could enter ALITHIOS, an ongoing, open-label, umbrella extension trial. Here, we analyze the cumulative data for up to 4 years of ofatumumab treatment (data cutoff: 25-Sep-2021) in the overall (N=1969), continuous (ofatumumab in core+extension; N=1292) and newly-switched (teriflunomide core and ofatumumab extension; N=677) groups. The proportion of patients with treatment-emergent adverse events (AEs), serious AEs, serious infections including opportunistic infections, and malignancies will be assessed. Laboratory parameters including neutrophils, lymphocytes, and serum immunoglobulin (Ig) G and IgM levels will be analyzed.

Results:

In data reported from ALITHIOS with a cut-off of 29-Jan-2021, representing ofatumumab treatment for up to ~3.5 years, 83.8% of patients had ≥1 AEs (exposure-adjusted incidence rate [EAIR], 148.7) and 9.7% had ≥1 serious AEs (EAIR, 4.8) with a low incidence of serious infections (2.9%; EAIR, 1.4) and malignancies (0.6%; EAIR, 0.3). Updated safety data representing continuous ofatumumab treatment for up to 4 years will be presented, focusing on the incidence of serious infections including opportunistic infections, incidence of malignancies, and deaths. The long-term trend of IgG/IgM levels and their association with serious infections will also be investigated.

Conclusions:

Safety findings for up to 3.5 years showed ofatumumab treatment to be well-tolerated with no new safety risks identified. This additional safety data will help confirm ofatumumab’s longer-term safety profile and provide further confidence to the MS community.

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