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Longer-Term Safety of Ofatumumab in Patients with Relapsing Multiple Sclerosis

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Abstract Text:

Background:

Ofatumumab, a fully human anti-CD20 monoclonal antibody with a 20 mg subcutaneous monthly dosing regimen, is approved for treating relapsing multiple sclerosis (RMS) in adults. In the Phase 3 ASCLEPIOS I/II trials, ofatumumab treatment up to 30 months had a favorable safety profile and was generally well-tolerated in RMS patients. Longer-term safety of ofatumumab in RMS patients continues to be monitored.

Objectives:

To assess the longer-term safety and tolerability of ofatumumab treatment for up to 4 years in patients with RMS.

Methods:

Patients completing the core ASCLEPIOS I/II, APOLITOS and APLIOS trials could enter ALITHIOS, an ongoing, open-label, extension study. We analyzed the cumulative safety data for up to 4 years of ofatumumab treatment (cut-off: 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 (TEAEs), serious AEs (SAEs), serious infections including opportunistic infections, and malignancies will be assessed. Laboratory parameters including neutrophils, lymphocytes, and serum immunoglobulin (Ig)G and IgM levels and association with serious infections will be analyzed.

Results:

Baseline demographics and disease characteristics of the overall group include: mean age±SD, 38.7±9.16 years; female, ~68%; mean±SD EDSS score, 2.87±1.38; mean±SD IgG levels, 10.28±2.21 g/L; mean±SD IgM levels, 1.27±0.66 g/L. In the previously reported data with a cut-off of 29-Jan-2021 (treatment for ~3.5 years), 83.8% of patients had ≥1 AEs (exposure-adjusted incidence rate/100 patient-years [EAIR], 148.7) and 9.7% had ≥1 SAEs (EAIR, 4.8) with an incidence of serious infections (2.9%; EAIR, 1.4) and malignancies (0.6%; EAIR, 0.3). Updated

cumulative clinical safety data of ofatumumab treatment for up to 4 years will be presented at the congress.

Conclusions:

Findings from ALITHIOS study for up to 3.5 years showed ofatumumab treatment to be well-tolerated with no new safety risks identified. This additional safety data up to 4 years will help to inform physicians on the longer-term safety profile of ofatumumab in RMS patients.

Title:

Longer-Term Safety of Ofatumumab in Patients with Relapsing Multiple Sclerosis

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Platform/Oral

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Disease-modifying therapy

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No

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Yes

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