Five-Year Safety of Ofatumumab in People Living With Relapsing Multiple Sclerosis

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INTRODUCTION

Previously reported safety data from ALITHIOS open-label extension study for up to 4 years demonstrated that extended treatment with ofatumumab continues to show a favorable safety and tolerability profile in relapsing multiple sclerosis (RMS) participants. Here, we assess the longer-term safety profile of ofatumumab treatment for up to 5 years.

METHODS

Participants completing core ASCLEPIOS I/II, APOLITOS and APLIOS clinical trials entered ALITHIOS. We analysed cumulative safety data for up to 5 years (cut-off: 25-Sep-2022) of ofatumumab treatment in the overall (N=1969), continuous (ofatumumab in core+extension; N=1292) and newly-switched (teriflunomide in core/ofatumumab in extension; N=677) groups. The analysis included the proportion of participants with treatment-emergent adverse events (AEs), serious AEs (SAEs), injection-related reactions (IRRs), serious infections including COVID-19, malignancies, serum immunoglobulin (Ig)G and IgM levels and their association with serious infections.

RESULTS

Overall, 89.9% of patients had ≥1 AEs (exposure-adjusted incidence rate/100 patient-years [EAIR], 124.6) and 14.7% had ≥1 SAEs (EAIR, 4.7) with low incidence of serious infections (5.4%; EAIR, 1.6) and malignancies (1.06%; EAIR, 0.3). Most COVID-19 cases were non-serious (92.3%) and recovered (96.1%) **(Table)**. Overall, 2% of patients had IgG and 30.6% had

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IgM <LLN (IgG: 5.65 g/L; IgM: 0.4 g/L) with no association between decreased IgG/IgM levels and risk of serious infections. No increase in risk of these AEs was observed.

CONCLUSIONS

Cumulative safety data for up to 5 years indicate that extended treatment with ofatumumab is well-tolerated, with no new safety risks identified. These data inform physicians on the longer-term safety profile of ofatumumab in people living with RMS.

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Table: Safety Profile of Ofatumumab for Up to 5 years of Treatment

Adverse event	Core, ASCLEPIOS OMB (N=946)		Core + extension, Overall OMB, (N=1969)	
	n (%)	EAIR (95% CI)	n (%)	EAIR (95% CI)
Patients with at least one AE	791 (83.61)	188.55 [175.86, 202.16]	1771 (89.9)	124.65 [118.97, 130.59]
Patients with at least one SAE	86 (9.10)	5.39 [4.36, 6.65]	289 (14.7)	4.68 [4.17, 5.26]
AEs leading to discontinuation	54 (5.70)	–	139 (7.1)	–
Infections and infestations	488 (51.58)	51.14 [46.80, 55.88]	1334 (67.75)	40.99 [38.85, 43.25]
Serious infections	24 (2.54)	1.44 [0.97, 2.15]	106 (5.38)	1.63 [1.35, 1.97]
Injection-related systemic reactions	195 (20.61)	15.49 [13.46, 17.83]	508 (25.79)	10.06 [9.22, 10.98]
Injection site reactions	103 (10.88)	7.21 [5.94, 8.74]	243 (12.34)	4.08 [3.60, 4.63]
Malignancies	5 (0.53)	0.32 [0.13, 0.77]	21 (1.06)	0.32 [0.21, 0.48]
Deaths	0	0	9 (0.46)	–

DISCLOSURES:

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