Poster DMT26

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Longer-Term Safety and Efficacy of Ofatumumab in People With Relapsing Multiple Sclerosis for Up to 6 Years

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KEY FINDINGS & CONCLUSIONS

- At Year 6, **9 of 10 participants** were **free of disease activity (no evidence of disease activity [NEDA-3])** in both the continuous and switch groups
  - Participants who were initially treated with teriflunomide (TER) had initially significantly lower rates of **NEDA-3**, but these rates **rapidly increased after switching to ofatumumab (OMB)**
- **Continuous OMB treatment** was associated with **fewer confirmed disability-worsening events up to 6 years** vs switching from TER, supporting the long-term benefit of **earlier initiation of OMB**, which cannot be recovered in those initially randomized to TER
- The sustained efficacy of OMB for up to 6 years was accompanied by a **consistent safety profile**, with no unexpected safety signals
  - The rate of adverse events, serious adverse events, serious infections, and malignancies **remained stable**, with no increased risk over 6 years
- Mean immunoglobulin (Ig) G levels **remained stable**, whereas mean IgM levels decreased but **remained above the lower limit of normal**; **no clinically meaningful association** between reductions in Ig levels and risk of serious infections was observed

These results support the long-term, favorable benefit–risk profile of OMB treatment (up to 6 years) and reinforce the benefit of early OMB initiation in people with relapsing multiple sclerosis

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INTRODUCTION

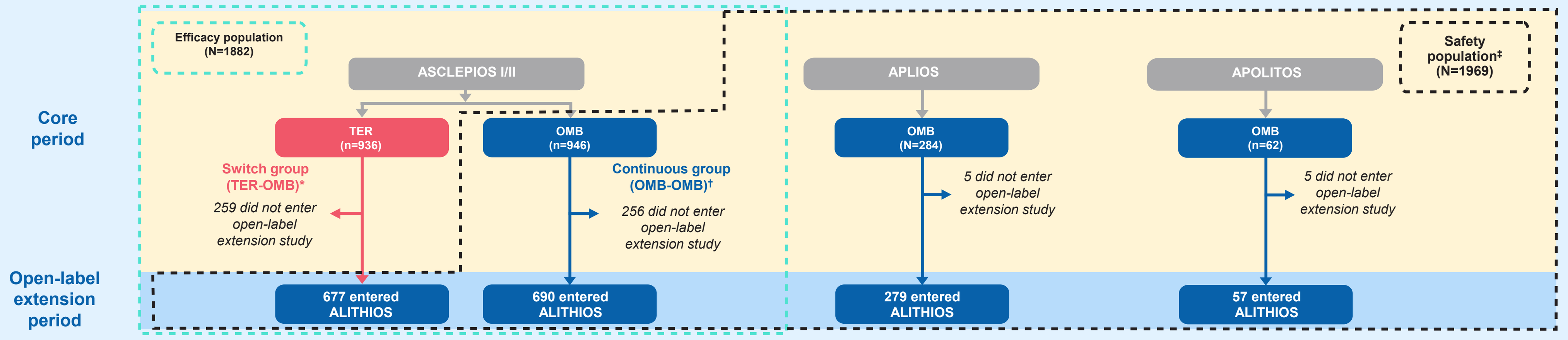
- Ofatumumab (OMB), a fully human anti-CD20 monoclonal antibody with a 20-mg subcutaneous monthly dosing regimen, is approved for treating relapsing multiple sclerosis (RMS) in adults[1]
  - In the United States, OMB is indicated for the treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- The phase 3 ASCLEPIOS I/II trials demonstrated the superiority of OMB (up to 30 months) compared with teriflunomide (TER) in reducing the clinical and magnetic resonance imaging disease activity while maintaining a favorable safety profile in people with RMS (pwRMS)[2]
- Treatment with OMB for up to 5 years showed sustained efficacy and a favorable safety profile during the ALITHIOS open-label extension study[3,4]
  - Data cutoff: September 25, 2022
- Longer-term safety and efficacy assessments are important to further understand OMB's benefit–risk profile in pwRMS

OBJECTIVE

- To assess the longer-term safety and efficacy of OMB treatment for up to 6 years (data cutoff: September 25, 2023) in pwRMS

METHODS

Figure 1. Participant Disposition and Key Assessments


Efficacy population (N=1882)
Safety population‡ (N=1969)
ASCLEPIOS I/II
APLIOS
APOLITOS
Core period
TER (n=936)
OMB (n=946)
OMB (n=284)
OMB (n=62)
Switch group (TER-OMB)*
Continuous group (OMB-OMB)†
259 did not enter open-label extension study
256 did not enter open-label extension study
5 did not enter open-label extension study
5 did not enter open-label extension study
Open-label extension period
677 entered ALITHIOS
690 entered ALITHIOS
279 entered ALITHIOS
57 entered ALITHIOS

Baseline demographics and participant characteristics of both safety and efficacy population represent a typical phase 3 MS population

Key assessments

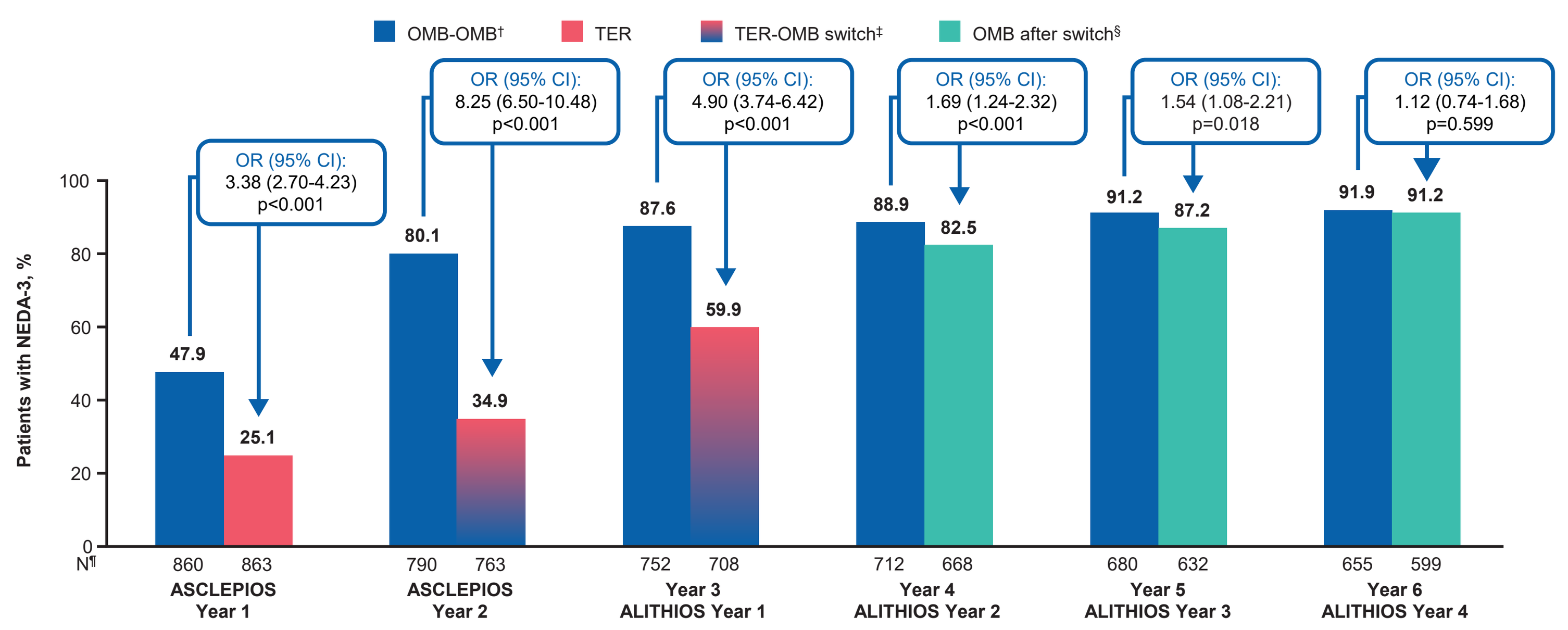
Efficacy§
- ARR
- Mean number of Gd+ T1 lesions per scan
- Number of neT2 lesions per year
- 6mCDW
- NEDA-3¶

Safety‖
- Overall safety profile
- Serious infections
- Laboratory parameters
  - IgG and IgM levels
  - Lymphocyte and neutrophil counts
- Malignancies

6mCDW, 6-month confirmed disability worsening; ARR, annualized relapse rate; Gd+, gadolinium-enhancing; Ig, immunoglobulin; MS, multiple sclerosis; NEDA-3, no evidence of disease activity; neT2 lesions, new or enlarging T2 lesions; OMB, ofatumumab; RMS, relapsing multiple sclerosis; TER, teriflunomide
*Participants who were randomized to TER in ASCLEPIOS I/II and switched to OMB during ALITHIOS; †Participants randomized to OMB in ASCLEPIOS I/II and continued OMB in ALITHIOS; ‡Participants who received ≥1 dose of OMB in ASCLEPIOS I/II, APLIOS, APOLITOS, or ALITHIOS; §Efficacy outcomes were analyzed in efficacy analysis set (N=1882); ¶NEDA-3 is defined as no 6mCDW, no confirmed MS relapse, no neT2 lesions, and no Gd+ T1 lesions; ‖Safety outcomes were analyzed in the safety analysis set (N=1969)

RESULTS

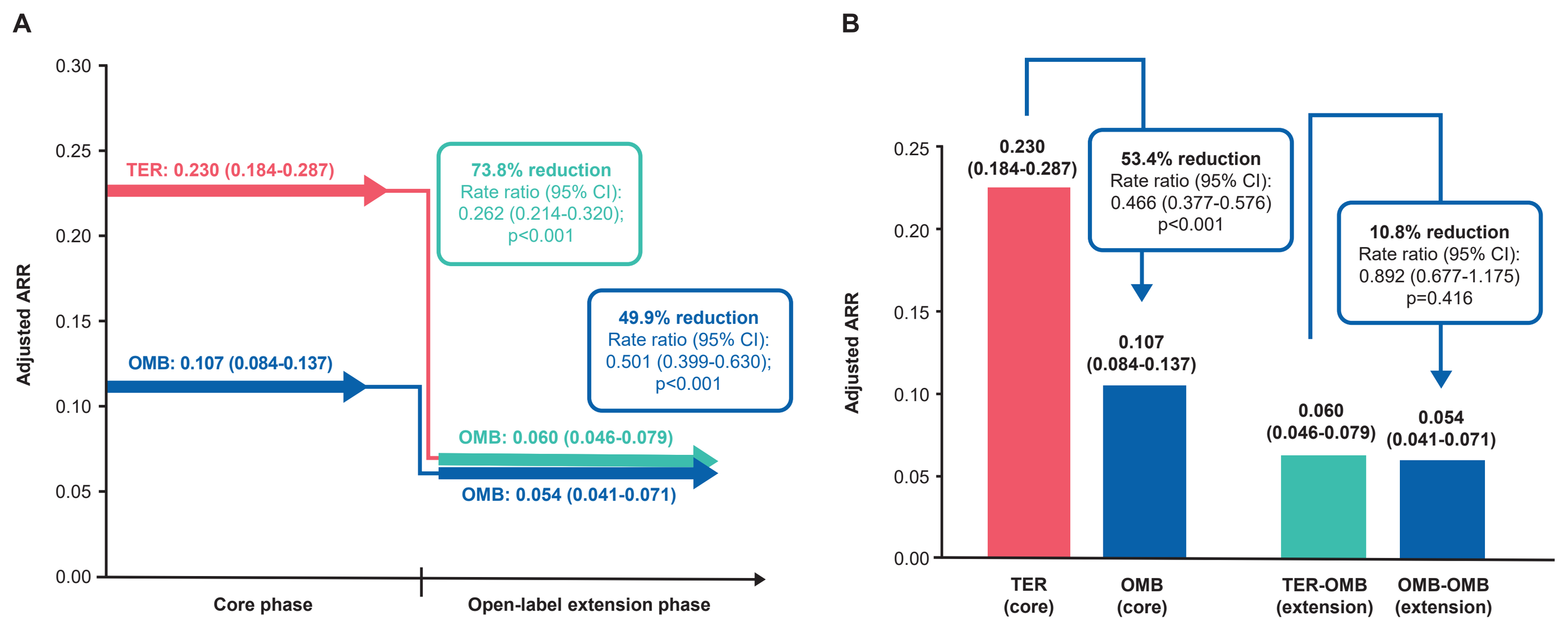
Figure 2. NEDA-3* Status After Up to 6 Years of OMB Treatment


OMB-OMB†
TER
TER-OMB switch‡
OMB after switch§
OR (95% CI): 3.38 (2.70-4.23) p<0.001
OR (95% CI): 8.25 (6.50-10.48) p<0.001
OR (95% CI): 4.90 (3.74-6.42) p<0.001
OR (95% CI): 1.69 (1.24-2.32) p<0.001
OR (95% CI): 1.54 (1.08-2.21) p=0.018
OR (95% CI): 1.12 (0.74-1.68) p=0.599
Patients with NEDA-3, %
47.9
25.1
80.1
34.9
87.6
59.9
88.9
82.5
91.2
87.2
91.9
91.2
N¶
860 863
790 763
752 708
712 668
680 632
655 599
ASCLEPIOS Year 1
ASCLEPIOS Year 2
Year 3 ALITHIOS Year 1
Year 4 ALITHIOS Year 2
Year 5 ALITHIOS Year 3
Year 6 ALITHIOS Year 4

6mCDW, 6-month confirmed disability worsening; Gd+, gadolinium-enhancing; MS, multiple sclerosis; NEDA-3, no evidence of disease activity; neT2, new or enlarging T2; OMB, ofatumumab; OR, odds ratio; TER, teriflunomide
*NEDA-3 is defined as no 6mCDW, no confirmed MS relapse, no neT2 lesions, and no Gd+ T1 lesions; †Continuous OMB; ‡Participants transitioning from TER to OMB; due to event-driven core study design (flexible duration), participants transitioned at various exposure time points (ie, the switch from TER to OMB started from Year 2 and was completed by Year 3); §TER participants now on OMB; ¶N is the total number of participants in the treatment group, excluding those who discontinued treatment early for reasons other than lack of efficacy or death and had NEDA-3 before early discontinuation

- At Year 6, 9 of 10 participants were free of disease activity (no evidence of disease activity [NEDA-3]) in the continuous and switch groups (**Figure 2**)
- There was a rapid initial increase in NEDA-3 with continuous OMB; high rates of NEDA-3 were maintained over 6 years (**Figure 2**)
  - ~90% of participants on continuous OMB achieved NEDA-3 within 3 years of starting treatment
- Participants who were initially on TER had significantly lower NEDA-3 rates, but a rapid increase in NEDA-3 was observed after switching to OMB, with >80% of patients achieving NEDA-3 within 1 year of switching (**Figure 2**)

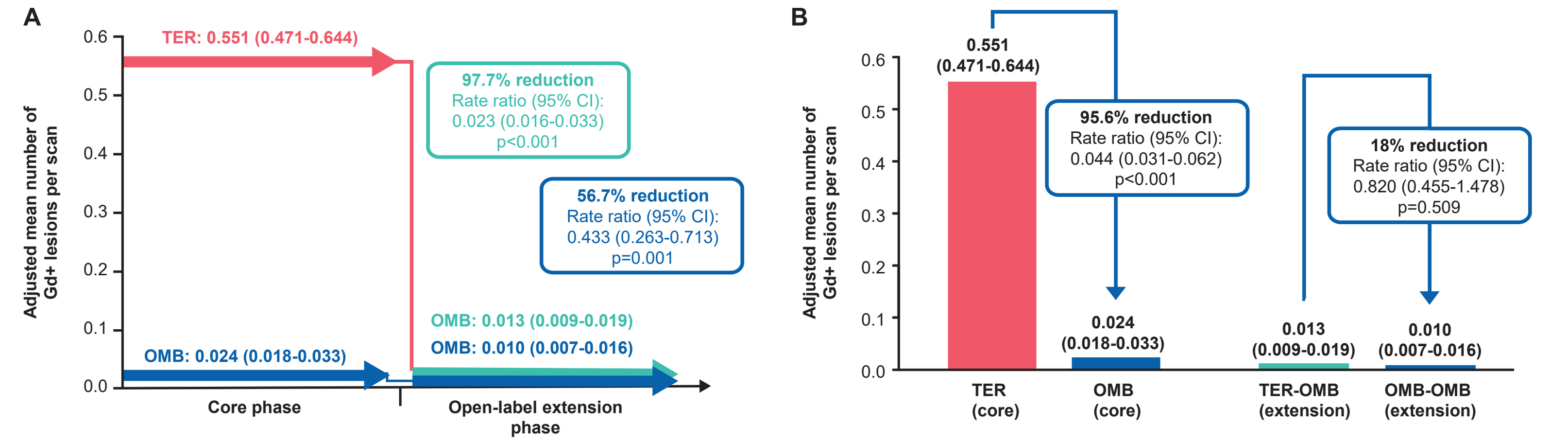
Figure 3. (A) Within-Group and (B) Between-Group Comparisons* Between the Core and Extension Phase (Continuous OMB and Switch Groups)


A
Adjusted ARR
TER: 0.230 (0.184-0.287)
73.8% reduction
Rate ratio (95% CI): 0.262 (0.214-0.320); p<0.001
OMB: 0.107 (0.084-0.137)
49.9% reduction
Rate ratio (95% CI): 0.501 (0.399-0.630); p<0.001
OMB: 0.060 (0.046-0.079)
OMB: 0.054 (0.041-0.071)
Core phase
Open-label extension phase
B
0.230 (0.184-0.287)
53.4% reduction
Rate ratio (95% CI): 0.466 (0.377-0.576) p<0.001
0.107 (0.084-0.137)
10.8% reduction
Rate ratio (95% CI): 0.892 (0.677-1.175) p=0.416
0.060 (0.046-0.079)
0.054 (0.041-0.071)
TER (core)
OMB (core)
TER-OMB (extension)
OMB-OMB (extension)

ARR, annualized relapse rate; EDSS, Expanded Disability Status Scale; Gd+, gadolinium-enhancing; OMB, ofatumumab; OMB-OMB, continuous ofatumumab; TER, teriflunomide; TER-OMB, switch from teriflunomide to ofatumumab
*ARRs are obtained from fitting a piecewise negative binomial model for the core phase and extension phase time period with log-link, adjusted for treatment and region as factors and number of relapses in previous year, baseline EDSS, baseline number of Gd+ lesions, and the participant's age at baseline as covariates. The natural log of the time-in-study (in years) by period is used as offset to annualize the relapse rate in each period. Baseline variables are from the core study baseline. All p-values are nominal p-values

- A sustained low annualized relapse rate (ARR) was observed in participants receiving OMB for up to 6 years (**Figure 3**)
  - Confirmed relapses are those accompanied by a clinically relevant change in the Expanded Disability Status Scale
- Continuous treatment with OMB up to 6 years was associated with a significant reduction in ARR by 49.9% (**Figure 3A**)
- A switch from TER to OMB resulted in a **pronounced reduction in ARR (73.8%)** (**Figure 3A**)
- A significant reduction in the ARR was observed for OMB vs TER in the core ASCLEPIOS I/II studies, and both groups receiving OMB in the extension study maintained a low ARR (**Figure 3B**)

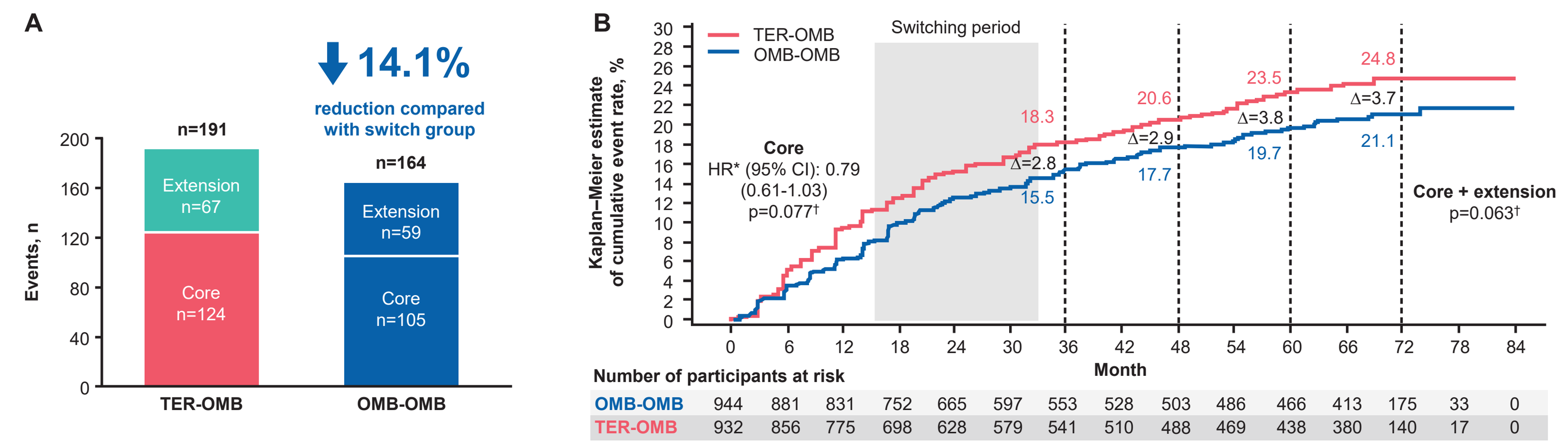
Figure 4. (A) Within-Group and (B) Between-Group Comparisons* Between the Core and Extension Phase for Gd+ T1 Lesions (Continuous OMB and Switch Groups)


A
Adjusted mean number of Gd+ lesions per scan
TER: 0.551 (0.471-0.644)
97.7% reduction
Rate ratio (95% CI): 0.023 (0.016-0.033) p<0.001
56.7% reduction
Rate ratio (95% CI): 0.433 (0.263-0.713) p=0.001
OMB: 0.013 (0.009-0.019)
OMB: 0.010 (0.007-0.016)
OMB: 0.024 (0.018-0.033)
Core phase
Open-label extension phase
B
0.551 (0.471-0.644)
95.6% reduction
Rate ratio (95% CI): 0.044 (0.031-0.062) p<0.001
18% reduction
Rate ratio (95% CI): 0.820 (0.455-1.478) p=0.509
0.024 (0.018-0.033)
0.013 (0.009-0.019)
0.010 (0.007-0.016)
TER (core)
OMB (core)
TER-OMB (extension)
OMB-OMB (extension)

Gd+, gadolinium-enhancing; OMB, ofatumumab; OMB-OMB, continuous ofatumumab; TER, teriflunomide; TER-OMB, switch from teriflunomide to ofatumumab
*Estimated from fitting a piecewise negative binomial model for the core phase and extension phase time period with log-link, adjusted for treatment as factor and baseline number of T1 Gd+ lesions and participant's age at baseline as covariates. The natural log of the number of scans with evaluable Gd+ lesion counts by period is used as offset to obtain the lesion rate per scan in each period. Baseline variables are from the core study baseline. All p-values are nominal p-values

- Gadolinium-enhancing (Gd+) T1 lesion activity remained almost completely suppressed in participants receiving OMB for up to 6 years (**Figure 4**)
- Continuous OMB treatment was associated with a significant reduction in the mean number of lesions per scan by 56.7% with longer-term treatment (**Figure 4A**)
- A switch from TER to OMB resulted in an almost complete suppression of Gd+ T1 lesion activity (97.7%) (**Figure 4A**)
- A significant reduction in the mean number of Gd+ T1 lesions was observed for OMB vs TER in the core ASCLEPIOS I/II studies (**Figure 4B**)
- Gd+ T1 lesions were almost completely suppressed during the extension phase in both the continuous OMB group and the switch group (**Figure 4B**)

Figure 5. (A) Cumulative Number of First 6mCDW Events; (B) Time to First 6mCDW Event


A
14.1%
reduction compared with switch group
Events, n
n=191
n=164
Extension n=67
Core n=124
Extension n=59
Core n=105
TER-OMB
OMB-OMB
B
TER-OMB
OMB-OMB
Switching period
Core
HR* (95% CI): 0.79 (0.61-1.03) p=0.077†
Core + extension p=0.063†
Month
Number of participants at risk
OMB-OMB 944 881 831 752 665 597 553 528 503 486 466 413 175 33 0
TER-OMB 932 856 775 698 628 579 541 510 488 469 438 380 140 17 0

Δ, difference in Kaplan–Meier estimates (TER-OMB minus OMB-OMB); 6mCDW, 6-month confirmed disability worsening; HR, hazard ratio; OMB, ofatumumab; OMB-OMB, continuous ofatumumab; TER-OMB, switch from teriflunomide to ofatumumab
Cutoff for the core and extension phases refers to the first dose of OMB in the extension phase
*HR was determined by Cox regression model; †p-Value represents log-rank test

- Earlier OMB treatment was associated with a lower number of 6-month confirmed disability worsening (6mCDW) events up to 6 years (**Figure 5**)
- Continuous use of OMB for up to 6 years resulted in a sustained reduction of 6mCDW events vs the switch group, highlighting the efficacy benefit that cannot be recovered in those initially randomized to TER (**Figure 5A**)
  - Rates of 6-month progression independent of relapse activity were also lower at 6 years with continuous OMB vs switch from TER (**Figure 5B**)
- Continuous OMB treatment was associated with a significantly lower number of 3-month confirmed disability worsening events (p<0.05) up to 6 years (**Figure 5**)

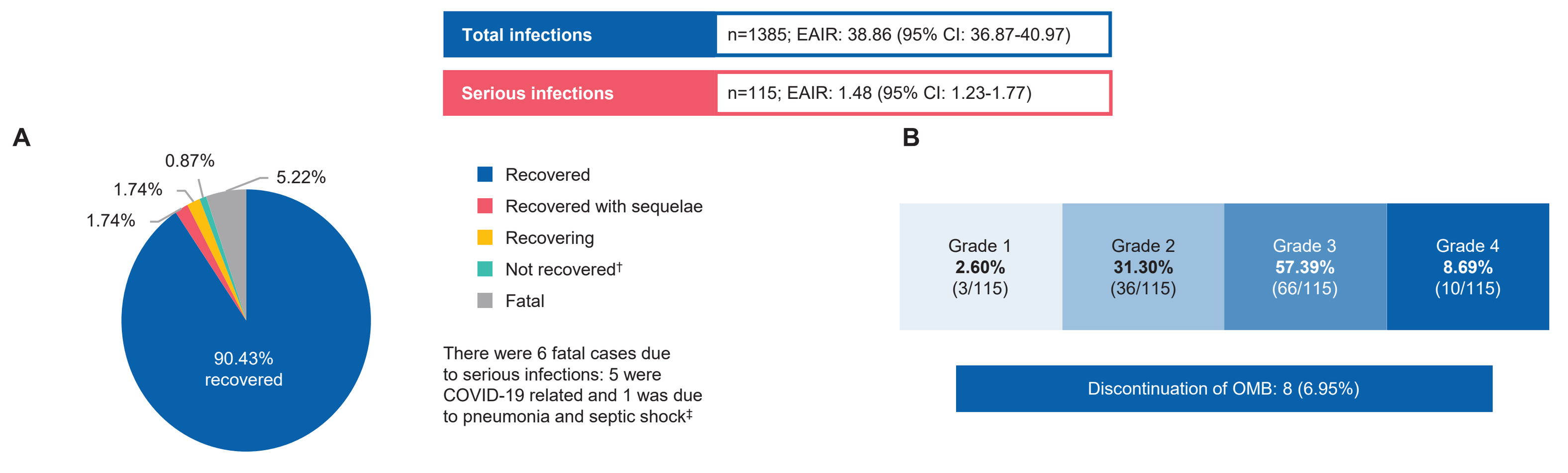
Table 1. Safety Profile of OMB With Up to 6 Years of Treatment

	Core, ASCLEPIOS*				Core + extension: overall OMB (N=1969)	
AE	OMB, n (%)	OMB, EAIR (95% CI)	TER, n (%)	TER, EAIR (95% CI)	n (%)	EAIR (95% CI)
Participants with ≥1 AE	791 (83.61)	188.55 (175.86-202.16)	788 (84.2)	188.92 (176.18-202.58)	1796 (91.2)	116.71 (111.44-122.24)
Participants with ≥1 SAE	83 (8.77)	5.56 (4.48-6.89)	73 (7.8)	4.94 (3.93-6.21)	323 (16.4)	4.40 (3.94-4.91)
AEs leading to OMB discontinuation	54 (5.70)	–	49 (5.2)	–	148† (7.5)	–
Infections and infestations	488 (51.58)	51.14 (46.80-55.88)	493 (52.7)	52.59 (48.14-57.44)	1385 (70.3)	38.86 (36.87-40.97)
Serious infections	24 (2.54)	1.55 (1.04-2.31)	17 (1.8)	1.12 (0.69-1.80)	115 (5.8)	1.48 (1.23-1.77)
Serious infections (excluding COVID-19)	24 (2.54)	1.55 (1.04-2.31)	17 (1.8)	1.12 (0.69-1.80)	71 (3.6)	0.90 (0.72-1.14)
Serious COVID-19 infections	0	0	0	0	49 (2.5)	0.62 (0.47-0.81)
Injection-related systemic reactions	195 (20.61)	15.49 (13.46-17.83)	143 (15.3)	10.90 (9.25-12.84)	514 (26.1)	8.50 (7.79-9.26)
Injection-site reactions	103 (10.88)	7.21 (5.94-8.74)	52 (5.55)	3.54 (2.70-4.65)	256 (13.0)	3.58 (3.17-4.05)
Malignancies	5 (0.53)	0.32 (0.13-0.77)	4 (0.4)‡	0.26 (0.10-0.69)	27 (1.4)	0.34 (0.23-0.49)
Deaths	0	–	1§	–	10¶ (0.5)	–

AE, adverse event; EAIR, exposure-adjusted incidence rate; Ig, immunoglobulin; OMB, ofatumumab; PY, patient-year; SAE, serious adverse event; TER, teriflunomide
EAIR per 100 PYs is defined as the expected number of patients with the given event over 100 years of exposure to a treatment, assuming the event rate is constant over time. This is estimated by Poisson regression where participants' time is taken until first event occurrence or the last day the patient was at risk for those who did not have the event
*Hauser 2020[2]; †AEs related to decreased IgM levels were the most common reason for treatment discontinuation (n=64 [3.3%]); ‡1 case of basal cell carcinoma was not listed as an SAE; §Death was due to aortic dissection; ¶Preferred terms for these 10 cases include: sudden death (n=1), completed suicide (n=1), COVID-19 and COVID-19 pneumonia (n=1), COVID-19 (n=2), intestinal metastasis (n=1), gastric ulcer perforation (n=1), pneumonia and septic shock (n=1), and pneumothorax and COVID-19 pneumonia (n=1)

- The safety profile of OMB remained consistent with up to 6 years of treatment (**Table 1**)
- Exposure-adjusted incidence rate (EAIR) per 100 patient-years (PYs) of adverse events (AEs) and serious AEs with up to 6 years of OMB treatment remained consistent with that in the ASCLEPIOS I/II trials, with no unexpected safety signals identified (**Table 1**)
- The most common AEs were infections (COVID-19 [34.3%], nasopharyngitis [20.6%], upper respiratory tract infection [14.9%], and urinary tract infection [14.4%]) (**Table 1**)
- EAIRs for malignancies did not increase over time in the overall safety population (**Table 1**)

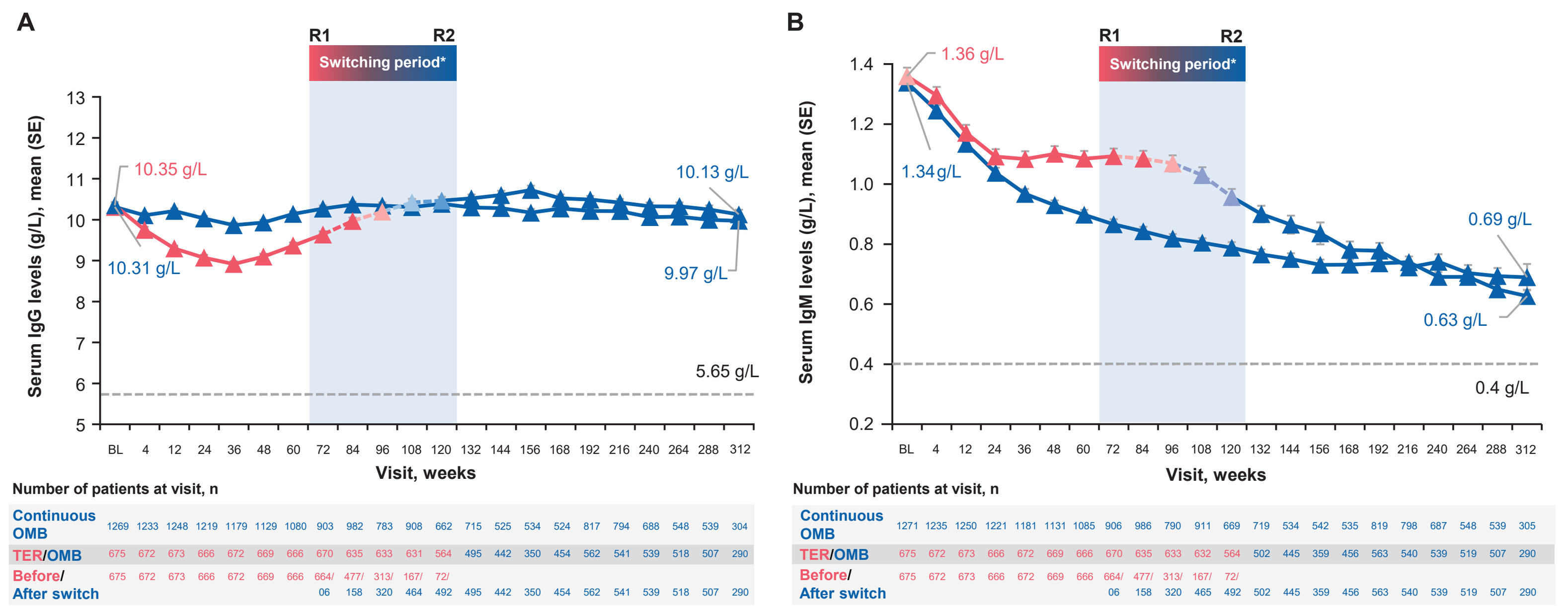
Figure 6. (A) Outcomes and (B) Severity of Serious Infections*


Total infections
n=1385; EAIR: 38.86 (95% CI: 36.87-40.97)
Serious infections
n=115; EAIR: 1.48 (95% CI: 1.23-1.77)
A
0.87%
5.22%
1.74%
1.74%
90.43% recovered
Recovered
Recovered with sequelae
Recovering
Not recovered†
Fatal
There were 6 fatal cases due to serious infections: 5 were COVID-19 related and 1 was due to pneumonia and septic shock‡
B
Grade 1 2.60% (3/115)
Grade 2 31.30% (36/115)
Grade 3 57.39% (66/115)
Grade 4 8.69% (10/115)
Discontinuation of OMB: 8 (6.95%)

EAIR, exposure-adjusted incidence rate; n, number of patients with ≥1 event; OMB, ofatumumab
*Severity grading was done by the investigator based on Common Terminology Criteria for Adverse Events version 5.0; †At the cutoff (September 25, 2023); ‡Unrelated to study drug; had medical history of kyphosis; treatment was discontinued due to pneumonia and septic shock

- The incidence of serious infections remained stable over time and did not increase with OMB treatment up to 6 years
- The overall EAIR per 100 PYs of serious infections was consistent with that in the phase 3 ASCLEPIOS I/II trials (EAIR: 1.55) and did not increase with treatment up to 6 years despite the COVID-19 pandemic; the most common serious infections were COVID-19 (1.4%)/COVID-19 pneumonia (1.3%) and appendicitis (0.8%) (**Figure 6**)
  - There were 49 COVID-19–related serious AEs in total: 1 of them had the preferred term of "suspected COVID-19", and the majority (85.71%) of the cases recovered; all cases of appendicitis recovered, and the majority of them were not related to OMB treatment
- One case of serious opportunistic infection of *Pneumocystis jirovecii* was reported; the final diagnosis was not confirmed by an external adjudication panel, and the clinical course was not suggestive of *P jirovecii* pneumonia; the participant had no change in dosage or interruption of OMB therapy and fully recovered (**Figure 6**)

Figure 7. Mean (A) IgG and (B) IgM Levels



Number of patients at visit, n (A)

Continuous OMB	1269	1233	1248	1219	1179	1129	1080	903	982	783	908	662	715	525	534	524	817	794	688	548	539	304
TER/OMB	675	672	673	666	672	669	666	670	635	633	631	564	495	442	350	454	562	541	539	518	507	290
Before/After switch	675	672	673	666	672	669	666	664/06	477/158	313/320	167/464	72/492	495	442	350	454	562	541	539	518	507	290

Number of patients at visit, n (B)

Continuous OMB	1271	1235	1250	1221	1181	1131	1085	906	986	790	911	669	719	534	542	535	819	798	687	548	539	305
TER/OMB	675	672	673	666	672	669	666	670	635	633	632	564	502	445	359	456	563	540	539	519	507	290
Before/After switch	675	672	673	666	672	669	666	664/06	477/158	313/320	167/465	72/492	502	445	359	456	563	540	539	519	507	290

BL, baseline; Ig, immunoglobulin; LLN, lower limit of normal; OMB, ofatumumab; R1, the first participant with a treatment-emergent assessment in the ofatumumab period after switching to ofatumumab (72 weeks); R2, the last participant with a treatment-emergent assessment in the teriflunomide period before switching to ofatumumab (120 weeks); TER, teriflunomide; TER-OMB, switch from teriflunomide to ofatumumab
*Refers to the participants who started on TER and is not applicable to the participants on OMB in the core period. For the TER-OMB group, data from the first dose of TER until the last dose of OMB plus 100 days or analysis cutoff date have been used. For all pooled analyses, a fixed value of LLN (using ALITHIOS study reference) was used: IgG: 5.65 g/L and IgM: 0.4 g/L

- Mean immunoglobulin (Ig) G levels remained stable up to 6 years of treatment; mean IgM levels decreased but remained above the lower limit of normal (LLN) (**Figure 7**)
- The majority of the participants had Ig levels above the LLN: 97.2% for IgG and 65.9% for IgM (**Figure 7**)
- Treatment interruptions/discontinuations were reported in 3 (0.2%)/4 (0.2%) participants, respectively, due to low IgG and 203 (10.3%)/71 (3.6%) participants, respectively, due to low IgM
- In ASCLEPIOS I/II, the investigators were required to interrupt study treatment if IgM levels fell 10% below LLN or IgG levels fell 20% below LLN; due to a protocol amendment at the beginning of ALITHIOS (June 3, 2021), the requirement to interrupt treatment based on a specific threshold due to low IgG/IgM was removed, and the decision was left to the discretion of the investigator
- No clinically meaningful association was observed between IgG/IgM levels <LLN and risk of serious infections

References

1. Novartis Pharmaceuticals Corporation. Prescribing information. Kesimpta® 2024. Accessed February 17, 2024. https://www.novartis.com/us-en/sites/novartis_us/files/kesimpta.pdf; 2. Hauser SL et al. *N Engl J Med*. 2020;383(6):546-557. 3. Cohen JA et al. Poster presented at: *AAN* 2023; P8.004. 4. Kappos L et al. Poster presented at: *EAN* 2023; EPR-097.

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Disclosures

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