

The Development of Ofatumumab, a Fully Human Anti-CD20 Monoclonal Antibody for Practical Use in Relapsing Multiple Sclerosis Treatment

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What are the key objectives of the article?

To discuss the clinical development and characteristics of ofatumumab (OMB) for the treatment of relapsing multiple sclerosis (RMS)

Global OMB clinical program in RMS

OMB is the first fully human low-dose anti-CD20 monoclonal antibody approved for treatment in adults with RMS¹⁻³

5 completed phase 2/3 clinical trials

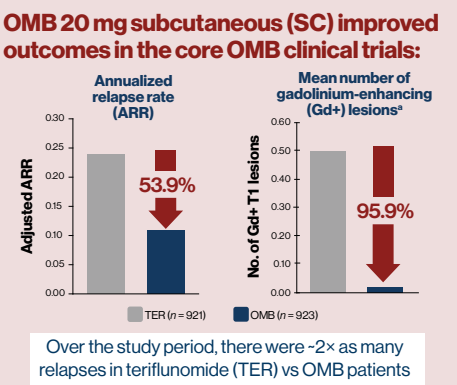
~37,127 patient treatment years of cumulative post-marketing exposure (as of Sept 2022)

1 ongoing long-term open-label extension study

EFFICACY

OMB rapidly reduced B-cell counts⁴⁻⁸

Rapid B-cell depletion that is sustained between monthly doses



SAFETY

Mean **immunoglobulin (Ig) G** levels remained **stable** and **IgM** levels remained within the **normal range**^{9,10}

Rapid B-cell repletion after treatment cessation⁸

For OMB- and TER-treated patients in the core OMB clinical trials:

Parameter	Ofatumumab (N = 946)	Teriflunomide (N = 936)
ASCLEPIOS I/II ≥1 Adverse event	83.6%	84.2%
Infections and infestations	51.6%	52.7%
Serious infections	2.5%	1.8%

Pooled data from the core OMB clinical trials confirmed a high level of efficacy and similar safety profile to TER for the OMB 20 mg SC regimen for relapsing forms of MS

TOLERABILITY

Injection-related reactions (IRRs) were primarily observed with the first injection¹¹:

Substantially decreased with further injections

The majority of IRRs (~99.8%) were mild/moderate¹¹

Low incidence of serious IRRs¹¹ with OMB 20 mg SC

98.8% of patients were compliant with OMB 20 mg SC in the core OMB trials¹²

ADMINISTRATION

At-home self-administration of OMB 20 mg SC:

- Convenience
- No need to visit infusion centers
- No pre-medication required
- Reduced burden (patients and healthcare centers) and costs

^aPer T1-weighted magnetic resonance imaging scan.

1. Bar-Or A, et al. CNS Drugs. 2021;35(9):985-997; 2. Novartis Ireland Ltd. KESIMPTA (ofatumumab) Summary of Product Characteristics. 2021. <https://www.ema.europa.eu/en/medicines/human/EPAR/kesimpta>. Accessed Dec 2022; 3. Kesimpta® US Prescribing Information. 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125326s0701bl.pdf. Accessed Dec 2022; 4. Hauser SL, et al. N Engl J Med. 2020;383(6):546-557; 5. Sorensen PS, et al. Neurology. 2014;82(7):573-581; 6. Bar-Or A, et al. Neurology. 2018;90(20):e1805-e1814; 7. Savelle M, et al. Mult Scler. 2022;28(6):910-924; 8. Yu H, et al. CNS Drugs. 2022;36(3):283-300; 9. Hauser SL, et al. Mult Scler. 2022;28(10):1576-1590; 10. Saccà F, et al. Oral presentation at: 8th European Academy of Neurology (EAN) Congress; Vienna, Austria; June 25-28, 2022, OPR134; 11. Bar-Or A, et al. Presented at: 8th Joint ACTRIMS-ECTRIMS Meeting; Virtual; September 11-13, 2020, 0316; 12. Alvarez E, et al. Mult Scler. 2022;28(3 suppl):P734.

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