About Kesimpta® (ofatumumab, formerly OMB157)

Media factsheet

What is Kesimpta?

Kesimpta is a targeted, precisely dosed and delivered B-cell therapy that has shown superior efficacy with a similar safety profile compared with teriflunomide.[1] Kesimpta is approved by the US Food and Drug Administration (FDA) for subcutaneous use, for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. It is the first B-cell therapy that can be self-administered once monthly at home via the Sensoready® autoinjector pen.[2]

How does it work?

Kesimpta efficiently targets B-cells, and its subcutaneous route of administration allows it to precisely deplete lymph B-cells, as shown in preclinical models, driving rapid and sustained B-cell depletion over the dosing period.[3] This means the B-cells are destroyed, helping to suppress the cascade of immune events contributing to MS disease activity. Consequently, there is a beneficial effect on disease activity and disease progression in patients living with MS.[1,4]

ASCLEPIOS I and II studies

The FDA approval was based on the Phase III ASCLEPIOS studies, which evaluated the safety and efficacy of Kesimpta 20 mg monthly subcutaneous injections versus teriflunomide 14 mg oral tablets taken once daily in adults with RMS.[1]

In the ASCLEPIOS I and II trials, Kesimpta demonstrated a significant reduction in the annualized relapse rate (primary endpoint) by 51% (0.11 vs 0.22) and 59% (0.10 vs 0.25) compared with teriflunomide (*P*<.001 in both studies), respectively.[1] The studies also evaluated secondary endpoints and compared with teriflunomide. Kesimpta:

- Demonstrated a relative risk reduction of 34.4% (*P*=.002) in 3-month confirmed disability progression (CDP).[1]
- Showed a significant reduction in the mean number of both gadolinium-enhancing (Gd+) T1 lesions (98% and 94% relative reduction, respectively, both *P*<.001) and new or enlarging T2 lesions (82% and 85% relative reduction, respectively, both *P*<.001).[1]
- Demonstrated a similar safety profile to teriflunomide, with the frequency of serious infections and malignancies also being similar across both treatment groups. Upper respiratory tract infection, headache, injection-related reactions, and local injection site reactions were the most commonly observed adverse reactions with Kesimpta (incidence greater than 10%).[1]

In a separate post hoc analysis, it was shown that Kesimpta may halt new disease activity with nearly nine out of 10 patients achieving no evidence of disease activity (NEDA-3) in their second year of treatment.[5]

References

1. Kesimpta Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corp; August 2020.
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3. Smith P, Huck C, Wegert V, et al. *Low-dose, subcutaneous anti-CD20 therapy effectively depletes B-cells and ameliorates CNS autoimmunity*. Poster presented at ECTRIMS; September 14–17, 2016; London, UK.
4. Bar-Or A, Grove RA, Austin DJ, et al. Subcutaneous ofatumumab in patients with relapsing-remitting multiple sclerosis: The MIRROR study. *Neurology.* 2018;90(20):e1805–1814.
5. Hauser S, Bar-Or A, Cohen JA, et al. Ofatumumab versus teriflunomide in relapsing multiple sclerosis: Analysis of no evidence of disease activity (NEDA-3) from ASCLEPIOS I and II trials. *Eur J Neurol*. 2020;27(1):261–263.