

MEDIA UPDATE

Novartis presents new four-year data on efficacy and safety of Kesimpta® (ofatumumab) in people living with relapsing multiple sclerosis

- *Phase 3 ASCLEPIOS I/II trials and the ALITHIOS open-label extension demonstrated the efficacy and safety of continuous Kesimpta® (ofatumumab) treatment and in those switched from teriflunomide, with no new safety risks identified over the treatment period^{1,2,3}*
- *Data showed that continuous treatment with Kesimpta for up to four years was associated with fewer relapses as well as reduced risk of three-month and six-month confirmed disability worsening and less lesion activity versus those who switched¹*
- *Interim analysis data from the ongoing KYRIOS open-label, prospective study showed that people living with relapsing multiple sclerosis vaccinated during stable Kesimpta treatment can mount an immune response to the COVID-19 mRNA vaccines, as soon as one week after initial vaccination⁴*
- *An analysis of injection-related reactions associated with subcutaneous administration of Kesimpta showed they were 99% mild to moderate in severity, with no life-threatening reactions⁵*

Basel, April 5, 2022 — Novartis today announced new long-term data from the Phase 3 ASCLEPIOS I/II trials and the ALITHIOS open-label extension that demonstrated long-term efficacy and safety of Kesimpta® (ofatumumab), with continued reduced risk of disability worsening, for people living with relapsing multiple sclerosis following up to four years of treatment¹. Kesimpta maintained a similar safety profile as seen in the pivotal Phase 3 trials up to four years of treatment, with no new safety risks identified over the treatment period^{1,2}. The data will be presented at the American Academy of Neurology (AAN) Annual Meeting being held on April 2–7, 2022 in Seattle, USA and virtually on April 24–26, 2022.

In addition to demonstrating efficacy up to four years of continuous treatment with Kesimpta, participants who switched from teriflunomide to Kesimpta in the extension phase demonstrated pronounced reductions in relapses and MRI lesions. In those receiving Kesimpta for up to four years, immunoglobulin G (IgG) levels remained stable and mean immunoglobulin M (IgM) levels decreased yet remained above the lower limit of normal, and no association between Ig levels and serious infection was observed. The overall rates of adverse events (AEs), serious AEs and overall rate of serious infections were consistent with those observed in the Phase 3 ASCLEPIOS I/II trials and did not increase with treatment up to four years despite the COVID-19 pandemic^{1,6}.

Data from the ongoing KYRIOS open-label, prospective study showed that people living with multiple sclerosis on Kesimpta can mount an immune response to the COVID-19 mRNA vaccine⁴. All participants in the study who were vaccinated during continuous Kesimpta treatment developed an immune response as soon as one week after initial vaccination. Immune response in participants who received a booster during treatment was similar to those who received a booster before treatment. In a study examining injection-related reactions (IRRs) associated with subcutaneous administration of Kesimpta in the ALITHIOS trial and from post-marketing reports, IRRs were mostly mild to moderate in severity (99%) with no medically confirmed fatal or life-threatening IRRs identified with Kesimpta⁵. These findings were consistent with those from the Phase 3 ASCLEPIOS I/II trials⁶.

“We are pleased to share long-term data of up to four years that support Kesimpta as an efficacious and well-tolerated, first-choice option for people living with relapsing multiple sclerosis. The sustained reductions in disability progression and lesion activity observed in those receiving continuous Kesimpta versus those who switched later from teriflunomide highlight the value of earlier treatment initiation with Kesimpta,” said Lykke Hinsch Gylvin, Neuroscience Global Medical Franchise Head, Novartis Pharmaceuticals. “In addition to these safety and efficacy data, we have presented findings that suggest people taking Kesimpta can mount an immune response to COVID-19 vaccination. During this pandemic, it is critical for people living with multiple sclerosis to have access to safe and efficacious treatments that do not interfere with their vaccine doses. Novartis is committed to continued research in multiple sclerosis with regards to COVID-19 vaccination and these data mark an additional milestone in this commitment.”

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system characterized by myelin destruction and axonal damage in the brain, optic nerves and spinal cord⁷. MS, which affects approximately 2.3 million people worldwide⁸, can be characterized into four main types: clinically isolated syndrome (CIS), relapsing-remitting (RRMS), secondary progressive (SPMS) and primary progressive (PPMS)⁹. The various forms of MS can be distinguished based on whether a patient experiences relapses (clearly defined acute inflammatory attacks of worsening neurological function), and/or whether they experience progression of neurological damage and disability from the onset of the disease¹⁰.

About Kesimpta® (ofatumumab)

Kesimpta is a targeted, precisely dosed and delivered B-cell therapy that provides the flexibility of self-administration for adults with relapsing forms of multiple sclerosis (RMS). It is an anti-CD20 monoclonal antibody (mAb) self-administered by a once-monthly injection, delivered subcutaneously^{11,12}. Initial doses of Kesimpta are at Weeks 0, 1 and 2, with the first injection performed under the guidance of a healthcare professional. As shown in preclinical studies, Kesimpta is thought to work by binding to a distinct epitope on the CD20 molecule inducing potent B-cell lysis and depletion¹³. The selective mechanism of action and subcutaneous administration of Kesimpta allows precise delivery to the lymph nodes, where B-cell depletion in MS is needed, and preclinical studies have shown that it may preserve the B-cells in the spleen¹⁴. Once-monthly dosing of Kesimpta differs from other anti-CD20 therapies as it allows faster repletion of B-cells, offering more flexibility in MS management¹⁰. Ofatumumab was originally developed by Genmab and licensed to GlaxoSmithKline. Novartis obtained rights for ofatumumab from GlaxoSmithKline in all indications, including RMS, in December 2015¹⁵.

Kesimpta has been approved for the treatment of relapsing forms of multiple sclerosis in the United States, European Union, United Kingdom, Canada, China, Switzerland, Singapore, Australia, Japan, Argentina, United Arab Emirates, Albania, and India.

Novartis in Neuroscience

At Novartis Neuroscience, we have been tackling neurological conditions for more than 80 years, launching transformative treatments which have made meaningful differences to millions of people worldwide. We continue to collaborate on industry-leading treatments in multiple sclerosis, pediatric neurology, neurodegeneration and neuropsychiatry because we know through innovation, partnership and community engagement early on, we can improve the standard of care.

To ensure patients everywhere can benefit from these life-changing therapies, we work closely with key stakeholders across the world to ensure rapid and sustainable access to our medicines, with the aim of providing the widest choice of treatments for each person's unique journey.

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About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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