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MEDIA UPDATE

Novartis publishes new five-year efficacy data on Kesimpta® (ofatumumab) for the treatment of relapsing multiple sclerosis

- *Continuous Kesimpta® (ofatumumab) treatment maintained profound suppression of MRI lesion activity and resulted in an increase in the number of patients with relapsing forms of multiple sclerosis (RMS) achieving NEDA-3 (no evidence of disease activity) for up to five years in the ALITHIOS open-label extension study*[1]

- *Patients who switched from teriflunomide to Kesimpta experienced a pronounced reduction of annualized relapse rates maintained through year five, with NEDA-3 rates increasing after switching to Kesimpta*[1]

- *The sustained five-year efficacy data combined with the well-tolerated five-year safety profile of Kesimpta*[2] *continue to support the favorable benefit-risk profile for Kesimpta in RMS patients*

Basel, June 30, 2023 — Novartis presents new long-term data from the ALITHIOS open-label extension study at the European Academy of Neurology (EAN) Annual Meeting held in Hungary on July 1-4, 2023.

Data showed the sustained efficacy of continuous Kesimpta® (ofatumumab) treatment over five years in patients with relapsing forms of multiple sclerosis (RMS).[1] Patients treated with Kesimpta experienced profoundly suppressed relapse rates, reduced MRI lesions and high rates of no evidence of disease activity (NEDA-3).[1] Patients who switched from teriflunomide to Kesimpta experienced pronounced reductions in relapse rates and MRI lesions. Although significantly fewer patients initially treated with teriflunomide achieved NEDA-3, the numbers increased substantially after switching to Kesimpta.[1]

“Continuous Kesimpta treatment for up to five years showed sustained efficacy with very low relapse rates, profound suppression of MRI lesions and increasing NEDA-3 rates” said principal investigator Ludwig Kappos, of the research center for Clinical Neuroimmunology and Neuroscience Basel. “Combined with its favorable safety profile, these findings support Kesimpta as a well-tolerated, efficacious treatment option for RMS patients.”

Data from the ALITHIOS open-label extension study showed that annualized relapse rates (ARR) remained low (ARR <0.05) for up to five years in the continuous Kesimpta group after starting treatment.[1] Gd+ T1 MRI and new / enlarging T2 MRI lesions were profoundly suppressed and the NEDA-3 status increased annually, indicating that Kesimpta leads to a decrease in disease activity, which resulted in more than 9 out of 10 patients (93.4%) achieving NEDA-3 at year 5.[1]

At the time of switching from teriflunomide to Kesimpta at year 2 to 3, the switch resulted in a pronounced reduction in ARR and was maintained through five years.[1] Further, switching to Kesimpta led to an increased suppression of MRI lesions, matching the continuous Kesimpta group and NEDA-3 rates increased after switching.[1]

These five-year efficacy data combined with the well-tolerated five-year safety profile of Kesimpta, presented at the American Academy of Neurology (AAN) Meeting 2023, continue to support the favorable benefit-risk profile for Kesimpta in RMS patients.[1,2]

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 cord[3]. MS, which affects around 2 million people worldwide[4], can be characterized into four main types: clinically isolated syndrome (CIS), relapsing-remitting (RRMS), secondary progressive (SPMS) and primary progressive (PPMS)[5]. 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 neurologic damage and disability from the onset of the disease[3].

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). Kesimpta is the first fully human anti-CD20 monoclonal antibody (mAb) self-administered by a once-monthly injection, delivered subcutaneously (SC) in RMS.[6,7,8] The treatment regimen was designed and tested to enhance safety and tolerability and minimize the risk of systemic injection-related reactions.[6] Initial doses of Kesimpta are at Weeks 0, 1 and 2, with the first injection performed under the guidance of a healthcare professional. Monthly Kesimpta 20 mg doses are associated with rapid reduction and near-complete peripheral B-cell depletion, with no significant effect on pharmacokinetics due to body weight.[6] 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 depletion.[9] The selective mechanism of action and SC 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 spleen.[10] Data from the ALITHIOS open-label extension study for up to 5 years and the ASCLEPIOS I/II core studies demonstrate Kesimpta's efficacy and favorable safety and tolerability profile in RMS participants.[11] The at-home administration of Kesimpta by monthly doses of 20 mg/0.4mL with an autoinjector (Sensoready®) also matches the preferences of many people living with MS due to its ease of use and supports patients to be compliant with, and persistent on the therapy over time.[6] Kesimpta was originally developed by Genmab and licensed to GlaxoSmithKline; Novartis obtained rights for ofatumumab from GlaxoSmithKline in all indications, including RMS, in December 2015.[12]

Kesimpta has been approved for the treatment of relapsing forms of multiple sclerosis in over 80 countries worldwide with more than 40 000 patients treated.

Novartis in Neuroscience

At Novartis, in Neuroscience, we are committed to understanding and solving some of the most burdensome neurological conditions to improve the quality of life for patients and their caregivers, and to make a positive impact on society. We aim to lead the discovery, development and delivery of innovative medicines to create a transformational impact for people living with severe neurological conditions by changing the course of disease progression.

Through innovation, partnerships and community engagement, we have been tackling neurological conditions for >80 years, launching transformative treatments which have made meaningful differences to millions of people worldwide. We continue to collaborate on the development of industry-leading innovative medicines for multiple sclerosis, and in the areas of neuroimmunology, neurodegeneration, and neuromuscular/rare diseases.
To ensure patients everywhere can benefit from these life-changing therapies, we work closely with key stakeholders across the world to ensure rapid access and sustainable accessibility to our medicines, with the aim of providing the best treatment choices for each person's unique journey.

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About Novartis
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