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MEDIA UPDATE

New Novartis data in relapsing MS reinforce benefits of Kesimpta® for first-line and switch patients

- *Nearly 90% of first-line Kesimpta patients had no disability progression independent of relapse activity (PIRA) for up to six years in an analysis of open-label ALITHIOS extension study*[1]
- *More than 80% of patients receiving first-line Kesimpta were progression-free for up to six years, reinforcing the value of introducing Kesimpta early*[1]
- *Patients switching to Kesimpta from IV anti-CD20 therapy showed no new active lesions (Gd+ T1) 12 months after switch in separate US single-arm, open-label, Phase IIIb OLIKOS study*[2]

Basel, September 18, 2024 – Novartis today announced new data from the ALITHIOS open-label extension study. Data show first-line Kesimpta® (ofatumumab) treatment for up to six years led to less disability and disease progression in recently diagnosed (≤3 years) and treatment-naïve (RDTN) people with relapsing multiple sclerosis (RMS), compared to those who switched from teriflunomide[1].

A separate US-based single-arm OLIKOS Phase IIIb study showed that at 12 months, all clinically stable RMS patients who switched from intravenous (IV) anti-CD20 therapy to Kesimpta showed no new gadolinium-enhancing (Gd+) T1 lesions, a commonly used marker of disease activity, compared to baseline[2].

These data will be presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) 2024 Annual Meeting in Copenhagen, Denmark on September 18-20.

“We continue to study the efficacy and safety of Kesimpta in different populations of people living with relapsing multiple sclerosis as part of our mission to advance care,” said Norman Putzki, M.D., Ph.D., Global Development Unit Head, Neuroscience & Gene Therapy, Novartis International AG. “Novartis is 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.”

Kesimpta benefits in first-line patients
Data from the overall ALITHIOS study population showed that continuous use of Kesimpta was associated with numerically fewer 6-month confirmed disability worsening (6mCDW) and progression independent of relapse activity (6mPIRA) events up to six years compared to those who switched from teriflunomide[1]. These benefits appeared more pronounced in the RDTN subgroup, defined as starting treatment within three years of diagnosis[1].

- RDTN patients receiving continuous Kesimpta were more likely to remain free from 6mCDW compared to those who switched to Kesimpta from teriflunomide (83.4% vs. 76.3%)[1].
- RDTN patients receiving continuous Kesimpta were also more likely to be free of 6mPIRA vs. switching from teriflunomide (88.9% vs. 83.3%)[1].

“These data showed that people recently diagnosed with relapsing multiple sclerosis who received first-line Kesimpta had fewer disability worsening events and greater likelihood of being progression-free,” said lead investigator Amit Bar-Or, M.D., Director of the Center for Neuroinflammation and Neurotherapeutics at the University of Pennsylvania. “The reduction of disability accumulation observed early in the disease course supports earlier adoption of Kesimpta.”

Limitations of the results include a potential for attrition bias and the open-label nature of the extension study[1].

No new T1 lesions in patients who switched from IV therapy to Kesimpta
The US-based OLIKOS study analyzed 102 clinically stable RMS patients who switched from previous IV anti-CD20 therapy (99% from ocrelizumab) to Kesimpta[2]. For 84 patients with MRI results, no new Gd+ T1 lesions were observed at 12 months, the study’s primary endpoint. Additionally, 98% of patients did not develop new/enlarging T2 (NeT2) lesions at 12 months, an exploratory endpoint in the study[2].

Treatment-emergent adverse events (TEAEs) occurred at a similar frequency as in the core Phase III ASCLEPIOS clinical trials, with no new safety signals identified[2]. The most commonly reported (≥10%) TEAEs were COVID-19, headache, fatigue, and urinary tract infection. Mean serum immunoglobulin G (IgG) and IgM levels remained stable up to 12 months[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 nearly 3 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). It is an anti-CD20 monoclonal antibody (mAb) self-administered by a once-monthly injection, delivered subcutaneously[6-9]. Initial doses of Kesimpta are at Weeks 0, 1 and 2, with the first injection performed under the guidance of a healthcare professional[6,7]. 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 spleen[10]. Ofatumumab was originally developed by Genmab and licensed to GlaxoSmithKline. Novartis obtained rights for ofatumumab from GlaxoSmithKline in all indications, including RMS, in December 2015[11].

Kesimpta has been approved for the treatment of relapsing forms of multiple sclerosis in over 90 countries worldwide with more than 100,000 patients treated as of August 2024[6,7,12].

Novartis in Neuroscience
At Novartis, we have been tackling neurological conditions for more than 80 years, launching transformative treatments which have made meaningful differences to millions of people worldwide now and in the future. We continue to collaborate on industry-leading

treatments in multiple sclerosis, pediatric neurology, neurodegeneration and neuroinflammation and psychiatry.

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About Novartis

Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people’s lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide.

Reimagine medicine with us: Visit us at **https://www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

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