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MEDIA UPDATE

New Novartis extension phase data show nearly 80% of RMS patients treated with Kesimpta® (ofatumumab) had no evidence of disease activity (NEDA-3)

- *New data from the Phase 3 ASCLEPIOS I/II trials and ALITHIOS open-label extension show that after four years nearly 8 out of 10 of people with relapsing multiple sclerosis (RMS) treated continuously with Kesimpta® (ofatumumab) had no evidence of disease activity (NEDA-3) compared with 5 out of 10 of those who switched to Kesimpta at a later date after initial teriflunomide treatment*[1]

- *Earlier initiation with Kesimpta resulted in a more than three-fold increased likelihood of maintaining NEDA-3 throughout the study, highlighting the importance of earlier initiation with a high efficacy therapy*[1]

- *An additional analysis presented from ASCLEPIOS I/II shows that treatment with Kesimpta was associated with significant improvements in cognitive processing speed (CPS) versus those treated with teriflunomide; these improvements were more pronounced in the subgroup of patients recently diagnosed with RMS*[2]

Basel, June 27, 2022 — Novartis today announced new data from the Phase 3 ASCLEPIOS I/II trials and the ALITHIOS open-label extension showing continuous treatment with Kesimpta® (ofatumumab) significantly increased the odds of achieving no evidence of disease activity (NEDA-3) versus switching from teriflunomide[1]. These data were presented at the European Academy of Neurology (EAN) Annual Meeting being held in Vienna, Austria and virtually on June 25–28, 2022.

These data show that after four years of treatment, 78.8% of those who continuously received Kesimpta achieved NEDA-3 (defined as having no MS relapses, no disability worsening and no MRI activity) versus only 51.8% of those who switched from teriflunomide to Kesimpta in the extension phase (odds ratio: 3.89; $p<0.001$)[1]. These data build on the previously presented efficacy data from ASCLEPIOS I/II and ALITHIOS showing sustained differences in cumulative relapses, MRI lesion activity and the risk of disability worsening between those who were continuously treated with Kesimpta versus those who switched at a later date[1].

“Early initiation of high-efficacy therapies for the treatment of relapsing multiple sclerosis has been shown to improve long-term outcomes versus escalating from lower efficacy therapies,” said Professor Ludwig Kappos, University Hospital Basel. “NEDA-3 is an important endpoint for physicians to consider when deciding to initiate high efficacy therapy, with this latest data from ALITHIOS we can clearly see the benefit of starting Kesimpta early versus switching to it later from teriflunomide.”

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 approximately 2.3 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[6].

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[7,8]. 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 depletion[9]. 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]. Once-monthly dosing of Kesimpta differs from other anti-CD20 therapies as it allows faster repletion of B-cells, offering more flexibility in MS management[6]. 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].

Ofatumumab 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 etc.

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.

Disclaimer
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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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