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MEDIA UPDATE

New peer-reviewed research shows no increased risk of serious COVID-19 infections in Kesimpta® (ofatumumab)-treated adults with multiple sclerosis

- *The study published in 'Neurology and Therapy' also shows the fatal outcomes and hospitalization rates due to COVID-19 in those treated with Kesimpta were in line with the rates in the general MS population reported in other studies*
- *A very small proportion (1.5%) of those treated with Kesimpta developed COVID-19 despite being fully or partially vaccinated, all these patients recovered; this is in line with the background rate of breakthrough infections in the fully vaccinated general population*
- *At the time of data cut-off, no cases of COVID-19 were reported after the booster vaccination*
- *Novartis is committed to generating evidence to better understand the severity and outcomes of COVID-19 in people receiving Kesimpta to help support informed decision making in RMS treatment selection.*

Basel, March 18, 2022 — Novartis today announced that the peer-reviewed journal *Neurology and Therapy*[1] has published new data on COVID-19 infections in people living with relapsing multiple sclerosis (RMS) treated with Kesimpta® (ofatumumab). This data was compiled from the ongoing, open-label, long-term extension phase 3b ALITHIOS study and from post-marketing reports submitted through the Novartis Global Safety Database.

Of the 1703 participants in ALITHIOS, 245 (14.3%) reported COVID-19, most cases were mild (44.1%) or moderate (46.5%) and the vast majority of patients recovered (98.4%).[1] The overall fatal outcome (0.8%) and hospitalization rates (9.4%) due to COVID-19 in Kesimpta-treated patients[1] were lower than the rates reported in the overall MS population (1.97% fatal outcome[2] and 15.5%-21.5% hospitalization[3]). Breakthrough COVID-19 infections occurred in 1.5% of fully vaccinated participants (n = 7/476), from which all recovered. This rate is aligned with the rate reported in the fully vaccinated general population (approximately 1.5%) during the time the study was carried out (as of 25 September 2021)[4,5], these rates are expected to rise as COVID-19 vaccine effectiveness wanes over time and new variants emerge. No cases of COVID-19 were reported after receiving a booster vaccination (n = 27) as per data cut-off in September 2021. The current data does not suggest any evidence of increased risk of severe COVID-19 in Kesimpta treated patients compared to the general population or other MS patients treated with or without disease-modifying therapies (DMTs).[1]

“Positive outcomes with regards to COVID-19 are important for people living with multiple sclerosis receiving disease-modifying therapies, especially after receiving a full course of vaccinations” said Lykke Hinsch Gylvin, Neuroscience Global Medical Franchise Head, Novartis Pharmaceuticals. “To date, this is one of the largest studies in people with RMS to report on COVID-19 cases post-vaccination, and we are very pleased with the results published today. While early reports during the pandemic raised concerns about COVID-19 in patients receiving certain disease-modifying therapies, this data shows that patients receiving Kesimpta have outcomes not dissimilar to the general population.”

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.[6] MS, which affects approximately 2.3 million people worldwide[7], can be characterized into four main types: clinically isolated syndrome (CIS), relapsing-remitting (RRMS), secondary progressive (SPMS) and primary progressive (PPMS).[8] 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.[9,10] 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.[11] 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.[12] 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.[13] 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.[14]

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.

About ALITHIOS study

The ALITHIOS study is an ongoing open-label, single-arm, multi-center extension Phase IIIb study evaluating the long-term safety, tolerability and effectiveness of ofatumumab in subjects with RMS who have participated in a Novartis ofatumumab clinical MS study. The primary endpoint is the number of patients that experience an adverse event or abnormal laboratory, vital and/or ECG results and positive suicidality outcomes. Secondary endpoints include number of relapse rates per year, 3- and 6-month CDW, 6-, 12- and 24-month confirmed disability improvement and improvement until end of study. This study includes a vaccination sub-study investigating the effects of ofatumumab on the development of antibody responses to selected vaccines and keyhole limpet hemocyanin (KLH) neo-antigen in subjects with RMS.[15]

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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