Kesimpta® (ofatumumab) data at AAN showed reduction in disability progression independent of relapse activity in newly diagnosed patients with RMS

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- *Kesimpta reduced the risk of disability progression independent of relapse activity (PIRA) by up to almost 60% vs first-line teriflunomide in a subgroup of newly diagnosed, treatment-naïve patients with relapsing forms of multiple sclerosis (RMS) according to new post hoc data from the Phase III ASCLEPIOS trials, further supporting Kesimpta as a first-choice treatment option for adults with RMS*[1]
- *More than 50% of confirmed disability worsening events in newly diagnosed, treatment-naïve RMS patients were PIRA, an emerging endpoint used in MS trials to measure disability worsening independent of relapses, indicating that disease progression starts early*[1]
- *Emerging open-label extension study data from the ALITHIOS trial showed that with this targeted B-cell therapy, precisely delivered through subcutaneous administration, mean serum IgM/IgG levels remained within the reference ranges over a three-year period to December 2020*[2]

East Hanover, April 16, 2021 — Novartis announced today new post hoc data from the Phase III ASCLEPIOS trials showing Kesimpta® (ofatumumab) reduced the risk of disability progression independent of relapse activity (PIRA) at three and six months vs teriflunomide in a subgroup of newly diagnosed, treatment-naïve patients with relapsing forms of multiple sclerosis (RMS).[1] These data, to be presented at the American Academy of Neurology (AAN) Annual Meeting being held virtually on April 17-22, 2021, further support Kesimpta as a first-choice treatment option for adults with RMS.

“This PIRA analysis shows more than half of the disability worsening events experienced by patients with early RMS were occurring regardless of whether they experienced relapses,” said Jacqueline A. Nicholas, MD, MPH, System Chief Neuroimmunology & MS, OhioHealth MS Center, Riverside Methodist Hospital, Columbus, Ohio. “Kesimpta reduced this risk of progression by up to almost 60% versus teriflunomide, reinforcing the importance of early intervention with high-efficacy treatment to address underlying disease progression before irreversible damage occurs.[1]”

“These findings add to the growing body of evidence that show RMS progression is silently occurring even in the early stages of disease, when relapses are less apparent,” said Victor Bultó, President, Novartis Pharmaceuticals Corporation. “To delay this disability worsening as soon as possible, it’s important for newly diagnosed patients to have the option of an at-home treatment with Kesimpta as a first choice, which delivers superior efficacy with a similar safety and tolerability profile compared with teriflunomide.”

All abstracts will be published in the journal *Neurology* following the meeting.

KESIMPTA

INDICATION

KESIMPTA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

Contraindication: KESIMPTA is contraindicated in patients with active hepatitis B virus infection.

Warnings and Precautions

Infections: An increased risk of infections has been observed with other anti-CD20 B-cell depleting therapies. KESIMPTA has the potential for an increased risk of infections including serious bacterial, fungal, and new or reactivated viral infections; some have been fatal in patients treated with other anti-CD20 antibodies. The overall rate of infections and serious infections in KESIMPTA-treated patients was similar to teriflunomide-treated patients (51.6% vs 52.7%, and 2.5% vs 1.8%, respectively). The most common infections reported by KESIMPTA-treated patients in relapsing MS (RMS) trials included upper respiratory tract infection (39%) and urinary tract infection (10%). Delay KESIMPTA administration in patients with an active infection until resolved.

Consider the potential increased immunosuppressive effects when initiating KESIMPTA after an immunosuppressive therapy or initiating an immunosuppressive therapy after KESIMPTA.

Hepatitis B Virus: *Reactivation:* No reports of hepatitis B virus (HBV) reactivation in patients with MS treated with KESIMPTA. However, HBV reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, has occurred in patients treated with ofatumumab at higher intravenous doses for chronic lymphocytic leukemia (CLL) than the recommended dose in MS and in patients treated with other anti-CD20 antibodies.

Infection: KESIMPTA is contraindicated in patients with active hepatitis B disease. Fatal infections caused by HBV in patients who have not been previously infected have occurred in patients treated with ofatumumab at higher intravenous doses for CLL than the recommended dose in MS. Perform HBV screening in all patients before initiation of KESIMPTA. Patients who are negative for HBsAg and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], should consult liver disease experts before starting and during KESIMPTA treatment.

Progressive Multifocal Leukoencephalopathy: No cases of progressive multifocal leukoencephalopathy (PML) have been reported for KESIMPTA in RMS clinical studies; however, PML resulting in death has occurred in patients being treated with ofatumumab at higher intravenous doses for CLL than the recommended dose in MS. In addition, JC virus infection resulting in PML has also been observed in patients treated with other anti-CD20 antibodies and other MS therapies. If PML is suspected, withhold KESIMPTA and perform an appropriate diagnostic evaluation. If PML is confirmed, KESIMPTA should be discontinued.

Vaccinations: Administer all immunizations according to immunization guidelines: for live or live-attenuated vaccines at least 4 weeks and, whenever possible at least 2 weeks prior to starting KESIMPTA for inactivated vaccines. The safety of immunization with live or live-attenuated vaccines following KESIMPTA therapy has not been studied. Vaccination with live or live-attenuated vaccines is not recommended during treatment and after discontinuation until B-cell repletion.

Vaccination of Infants Born to Mothers Treated with KESIMPTA During Pregnancy. For infants whose mother was treated with KESIMPTA during pregnancy, assess B-cell counts prior to administration of live or live-attenuated vaccines. If the B-cell count has not recovered in the infant, do not administer the vaccine as having depleted B-cells may pose an increased risk in these infants.

Injection-Related Reactions: Injection-related reactions with systemic symptoms occurred most commonly

within 24 hours of the first injection, but were also observed with later injections. There were no life-threatening injection reactions in RMS clinical studies.

The first injection of KESIMPTA should be performed under the guidance of an appropriately trained health care professional. If injection-related reactions occur, symptomatic treatment is recommended.

Reduction in Immunoglobulins: As expected with any B-cell depleting therapy, decreased immunoglobulin levels were observed. Monitor the levels of quantitative serum immunoglobulins during treatment, especially in patients with opportunistic or recurrent infections and after discontinuation of therapy until B-cell repletion. Consider discontinuing KESIMPTA therapy if a patient with low immunoglobulins develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.

Fetal Risk: Based on animal data, KESIMPTA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to KESIMPTA in utero. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 B-cell depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving KESIMPTA and for at least 6 months after the last dose.

Most common adverse reactions (>10%) are upper respiratory tract infection, headache, injection-related reactions, and local injection-site reactions.

Please see full Prescribing Information, including Medication Guide.

About Novartis

Located in East Hanover, NJ Novartis Pharmaceuticals Corporation – an affiliate of 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 employs nearly than 16,000 people in the United States. For more information, please visit https://www.novartis.us.

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2. Cross AH, Delgado S, Habek M, et al. Characteristics and outcome of COVID-19 in patients with relapsing multiple sclerosis receiving ofatumumab. ePoster presentation at Virtual AAN Meeting; April 2021.
