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MEDIA UPDATE

Kesimpta® (ofatumumab) data show long-term preservation of IgG/IgM levels and no increased risk of serious infections in people living with multiple sclerosis

- *New ALITHIOS data show mean immunoglobulin G (IgG) levels in people treated with Kesimpta remained unchanged over 3.5 years and mean immunoglobulin M (IgM) levels remained within the reference range*[1]
- *Lower serum immunoglobulin levels, known to occur with other anti-CD20 therapies in MS patients, have been linked to an increased risk of infection, while immunoglobulin data with Kesimpta showed no association with risk of serious infections*[1, 2, 3]
- *Data plan for the ALITHIOS sub-study on antibody-mediated immunity post-vaccination in Kesimpta-treated patients will be presented; data generated will provide greater understanding of how the B-cell depleting treatment will impact immune response to vaccinations*[1]
- *Kesimpta is a targeted B-cell therapy that delivers superior efficacy with a similar safety and tolerability profile compared with teriflunomide, a first-line treatment in MS*[4]

Basel, June 22, 2021 — Today, Novartis disclosed new data showing mean IgG and IgM levels remain unchanged in adults with relapsing multiple sclerosis (RMS) treated with Kesimpta® (ofatumumab) over 3.5 years. The ongoing open label extension of the ALITHIOS study includes 1,703 people living with MS taking Kesimpta for up to 5 years. At the time of analysis, 456 of these people had reached 3.5 years of Kesimpta treatment duration. The long-term findings were consistent with the Phase III ASCLEPIOS trials data, which demonstrated that the overall incidence of infections was low, and no association was observed between decreased immunoglobulin levels and the risk of serious infections[1]. These data reinforce Kesimpta as a well-tolerated treatment option for people living with RMS.

“Evidence shows that low immunoglobulin levels have been linked to an increased risk of infection, which is why testing of these levels is recommended for people living with MS prior to taking any anti-CD20 treatment,” said Professor Heinz Wiendl, Director of the Clinic of Neurology at UKM Münste. “It’s encouraging to see that over a long period of time, IgG levels remained stable and IgM levels remained well within the reference ranges in all groups treated with ofatumumab, with no increased risk of infections.”

The results will be presented at the 7th Congress of the European Academy of Neurology – Virtual 2021, together with other wide-ranging data to further the understanding of how Kesimpta might impact immune response to a variety of standard vaccinations.

“Patient safety is of the utmost importance to Novartis and these long-term results continue to support Kesimpta as a high-efficacy, first-choice treatment with a favorable safety profile for people living with RMS,” said Marcia Kayath, Global Head Medical Affairs, Novartis Pharmaceuticals. “Preservation of immunoglobulin levels is important to fight infections, like COVID-19, so we’re very happy to share long-term data showing Kesimpta had unchanged IgG levels, providing physicians with important information relevant to the long-term benefit/risk of treating with Kesimpta.”

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