

## MEDIA UPDATE

# Novartis peer-reviewed safety and tolerability data further strengthens Kesimpta's (ofatumumab) favorable benefit-risk profile in patients with relapsing multiple sclerosis

- *Multiple Sclerosis Journal* has published data from the ALITHIOS open-label extension study which provide a robust picture of the continuous safety data for Kesimpta, showing it was well tolerated in ~2000 patients with up to 3.5 years exposure with no new safety risks identified<sup>1</sup>
- Immunoglobulin G (IgG) levels remained stable in patients treated up to 3.5 years and mean immunoglobulin M (IgM) levels decreased yet remained above the lower limit of normal in most patients treated with Kesimpta<sup>1</sup>
- Lower serum immunoglobulin (Ig) levels, which have been observed in anti-CD20 therapies, have been linked to an apparent increased risk of infection<sup>2</sup>; while immunoglobulin data with Kesimpta showed no association with risk of serious infections<sup>1</sup>
- No opportunistic infections were identified and observed COVID-19 infections showed no evidence of an increase in incidence or severe outcomes in Kesimpta-treated patients<sup>1</sup>
- 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<sup>1</sup>

**Basel, March 2, 2022** — Today, Novartis announced that new data from the ALITHIOS open-label extension study was published in the peer-reviewed *Multiple Sclerosis Journal*. The data showed that with up to 3.5 years of treatment with Kesimpta® (ofatumumab), no incidences of opportunistic infections were reported, and observed COVID-19 infections showed no evidence of an increase in incidence or severe outcomes in adults with relapsing forms of multiple sclerosis (RMS)<sup>1</sup>. Mean immunoglobulin G (IgG) levels remained stable and immunoglobulin M (IgM) levels remained above the lower limit of normal in most patients. The overall incidence of serious infections was low and no new safety risks were identified. This study, which included 1,969 RMS patients, provides a robust picture of the continuous safety data for Kesimpta<sup>1</sup>.

“The cumulative safety data suggest that treatment with Kesimpta over an extended period of time is well tolerated in adults with RMS and support the long-term use of Kesimpta in all RMS patients, including early MS patients<sup>1</sup>,” said Lykke Hinsch Gylvin, Neuroscience Global Medical Franchise Head, Novartis Pharmaceuticals. “While low serum immunoglobulin

observed with anti-CD20 therapies have historically been linked with an apparent risk of serious infection, immunoglobulin data seen with Kesimpta over extended exposure showed that mean Ig levels remained within reference ranges with a low overall incidence of serious infection, including COVID-19. These data give confidence to people living with MS and their prescribing physicians, and further support Kesimpta as a potential first-choice treatment option for RMS.”

#### **About Kesimpta® (ofatumumab)**

Kesimpta is a targeted, precisely dosed and delivered B-cell therapy that provides the flexibility of self-administration for adults with RMS. It is an anti-CD20 monoclonal antibody (mAb) self-administered by a once-monthly injection, delivered subcutaneously<sup>3,4</sup>. Initial doses of Kesimpta are given 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<sup>5</sup>. 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<sup>6</sup>. Once-monthly dosing of Kesimpta also allows faster repletion of B-cells and offers more flexibility<sup>7</sup>. 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<sup>8</sup>.

#### **About ALITHIOS study**

The ALITHIOS study is an ongoing open-label, single-arm, multi-center 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<sup>9</sup>.

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### **References**

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