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MEDIA UPDATE

Kesimpta® (ofatumumab) data at ECTRIMS highlights preservation of IgG levels and safety experience over extended exposure (~3.5 years) in people living with relapsing multiple sclerosis

- *ALITHIOS Phase IIIb open-label extension study data based on ~3.5 years of exposure demonstrated that mean immunoglobulin G (IgG) levels in patients treated with Kesimpta remained stable, and there was no apparent association between decreased IgG levels and the risk of serious infections*[1]
- *ALITHIOS Phase IIIb open-label extension study data also showed mean immunoglobulin M (IgM) levels declined over time but remained within the reference range for the majority of patients. The overall incidence of serious infections was low*[1]
- *Additional ALITHIOS data showed 94% (n=139) of COVID-19 cases were mild or moderate in severity in adults treated with the B-cell targeting therapy*[2]
- *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 multiple sclerosis (MS)*[3]

Basel, October 14, 2021 — Today, Novartis announced data demonstrating the safety of Kesimpta® (ofatumumab) over extended exposure (~3.5 years) in patients with relapsing forms of multiple sclerosis (RMS).[1] These data—presented at the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) taking place virtually, October 13–15, 2021— further support Kesimpta as a potential first-choice treatment option for adults with active RMS, including newly diagnosed patients.[1]

“Antibodies, also known as immunoglobulins, function as part of the healthy immune system, and reduced serum immunoglobulin levels have been previously linked to an apparent increased risk of infection. We are therefore encouraged by the results demonstrating that these levels remained within the reference range for patients taking Kesimpta,” said Lykke Hinsch Gylvin, Neuroscience Global Medical Franchise Head, Novartis Pharmaceuticals. “Providing safe and well-tolerated treatments with superior efficacy is of the utmost importance to Novartis in our continued efforts to reimagine MS care and improve the lives of people living with MS.”

These data build on previous efficacy and safety findings including the Phase III ASCLEPIOS I and II studies, in which Kesimpta demonstrated superiority versus teriflunomide in significantly reducing the annualized relapse rate (ARR, primary endpoint), 3-month confirmed disability progression (CDP), and the number of gadolinium-enhancing (Gd+) T1 and new or enlarging T2 lesions.[3]

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References

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3. Hauser S, Bar-Or A, Cohen J, et al. Ofatumumab versus teriflunomide in relapsing multiple sclerosis. *N Engl J Med*. 2020;383(6):546-557.

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