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MEDIA UPDATE

Novartis to present broad range of portfolio data at ECTRIMS, reinforcing long-standing commitment to people living with multiple sclerosis

- *Novartis will present 41 abstracts from a wide-ranging multiple sclerosis (MS) portfolio, including new data on Kesimpta® (ofatumumab) and Mayzent® (siponimod)*
- *Novartis will be commencing Phase III pivotal trials investigating remibrutinib in RMS. Remibrutinib is a highly selective, potent oral BTK inhibitor with a potential best-in-class profile[1]*
- *Late-breaking safety data will be presented, including outcomes of COVID-19 in relapsing forms of multiple sclerosis (RMS) patients treated with Kesimpta[2], and effects of Kesimpta on immunoglobulin levels and risk of infection based on ~ 3.5 years of exposure[3]*
- *Design of a new open-label study assessing immune response to SARS-CoV-2 mRNA vaccines in MS-patients treated with Kesimpta[4], and new findings from open-label study assessing immune response to SARS-CoV-2 mRNA vaccines in secondary progressive MS (SPMS) patients treated with Mayzent will be presented[5]*

Basel, October 7, 2021 — Novartis announced today it will present 41 abstracts at the upcoming 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), taking place digitally on October 13-15, 2021. The data being presented spans a comprehensive MS portfolio, emphasizing the company's commitment to improving the quality of life for people living with MS at all stages of the disease.

"These data strengthen the role of Kesimpta as a first-choice treatment for relapsing forms of MS, highlighting its long-term safety and efficacy for patients and physicians," said Lykke Hinsch Gylvin, Neuroscience Global Medical Franchise Head, Novartis Pharmaceuticals. "With new data across our MS portfolio, Novartis is committed to reimagining medicine by leading on new treatment options, challenging ourselves to focus on unmet needs when managing the disease, and ultimately improving the lives of people living with MS."

In addition to the data presented at ECTRIMS, Novartis will initiate Phase III pivotal trials to investigate remibrutinib in RMS patients. Remibrutinib (LOU064) is a highly selective and

potent covalent BTK inhibitor with a potential best-in-class profile and has shown favorable safety based on clinical data established to date.[1]

BTK inhibitors are a novel class of therapies that target B-cells and other innate immune cells and prevent inflammation and potentially disease progression in MS.

Novartis key highlights at the 37th ECTRIMS Congress include:

New efficacy and safety data on Kesimpta, the first and only self-administered, targeted B-cell therapy for patients with relapsing forms of MS (RMS), show that Kesimpta is a well-tolerated, high-efficacy therapy in adults, including newly diagnosed patients, with RMS. The study results will provide a robust picture of safety data for Kesimpta after extended exposure (~ 3.5 years):

- New findings from the ALITHIOS Phase IIIb open-label extension study look at immunoglobulin M (IgM) and immunoglobulin G (IgG) levels in people treated with Kesimpta over ~ 3.5 years to better understand the potential effect of ofatumumab on these antibody levels as well as any association with risk of serious infection during continuing observation.[3]
- Safety and efficacy data on Kesimpta from the ALITHIOS Phase III study look at RMS-patients treated with Kesimpta and their risk of a COVID-19 infection as well as its severity.[2]
- Interim results from a single-center study in the US show the effect of Kesimpta on microglial activation.[6]
- An open-label multicenter single-arm pilot study in the US will assess the immune response to SARS CoV-2 mRNA vaccine in MS-patients treated with Kesimpta.[4]

New data on Mayzent, the first and only oral treatment studied and proven to slow disability progression as demonstrated in the EXPAND study that included a broad range of secondary progressive MS (SPMS) patients, add to the growing body of evidence that patients treated with Mayzent show delays in disability progression and experience benefits in cognitive performance:

- An open-label, three-cohort, prospective study based in Germany will present interim data on the immune response after SARS CoV-2 mRNA vaccination in SPMS-patients treated with Mayzent.[5]
- Findings from the ongoing EXPAND extension study on the long-term outcomes with Mayzent, showing continuing sustained efficacy of the treatment in patients receiving Mayzent.[7]
- Real world and phase III study data combined to characterize the extent and patterns of activity in ‘active’ and ‘non-active’ SPMS demonstrates that such definitions can be unreliable and may lead to suboptimal management of people living with SPMS.[8]
- A retrospective real-world study will review patient self-reported and physician-reported information on cognitive symptoms, thus examining the discordance between physician and patient perception of cognition impairment.[9]

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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