Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

https://www.novartis.com
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MEDIA UPDATE

Novartis data at ACTRIMS-ECTRIMS highlight the strength of leading multiple sclerosis (MS) portfolio with life-changing therapies for people across the MS spectrum

- *Novartis will present 48 abstracts from its leading MS portfolio, including new data on recently FDA-approved Kesimpta® (ofatumumab)—the first and only self-administered, targeted B-cell therapy for relapsing forms of MS (RMS)—Mayzent® (siponimod) and Gilenya® (fingolimod)*

- *New pivotal data from ASCLEPIOS trials evaluating the efficacy and safety of Kesimpta in a subgroup of treatment-naïve RMS patients will be presented for the first time[1]*

- *Subgroup analyses of the EXPAND trial showed sustained benefits on disability, cognitive processing speed and relapse outcomes for up to five years in patients with active secondary progressive multiple sclerosis (SPMS) treated continuously with Mayzent, highlighting potential value of early treatment initiation[2]*

- *Findings from real-world study show MSProDiscuss™ tool is valuable in facilitating MS progression-related conversations with patients in daily practice[3]*

Basel, September 8, 2020 — Novartis announced today it will present 48 abstracts at the upcoming MSVirtual2020: 8th Joint ACTRIMS-ECTRIMS Meeting, September 11–13, 2020. The breadth of data being presented highlights the strength and promise of the company's MS portfolio to improve the lives of patients across the MS spectrum.

"As a global leader in neuroscience, we have been committed to bringing life-changing therapies to people living with diseases like MS for more than 75 years," said Estelle Vester-Blokland, Global Head Neuroscience Medical Affairs, Novartis Pharmaceuticals. "For the first time in our growing portfolio, we are proud to be presenting data from three of our approved MS treatments across the MS disease spectrum, which is a significant milestone of our commitment to reimaging medicine for the MS community."

Novartis key highlights at MSVirtual2020: 8th Joint ACTRIMS-ECTRIMS Meeting include:

New efficacy and safety data on Kesimpta, the first and only self-administered, targeted B-cell therapy for patients with relapsing MS (RMS), indicate potential benefits of starting high-efficacy therapy early with Kesimpta. Kesimpta was approved by the US Food and Drug

Administration (FDA) for treatment in RMS to include clinically isolated syndrome, relapsing–remitting disease and active secondary progressive disease in adults, in August 2020[4]:

- New findings from the ASCLEPIOS Phase III trials demonstrate Kesimpta's superior efficacy vs teriflunomide in newly diagnosed, treatment-naïve patients with low absolute relapse rates, very low magnetic resonance imaging (MRI) lesion activity and prolonged time to disability worsening[1].
- Additional safety and efficacy data on Kesimpta show that no new safety signals were identified in patients treated with Kesimpta. In this extended analysis, Kesimpta showed a safety profile that remains consistent with data reported in the Phase II and III clinical trials[5].
- Results from the ASCLEPIOS trials also demonstrated that baseline serum neurofilament light levels (sNfL) were prognostic for lesion formation and brain volume loss for at least two years. These results support that sNfL can complement clinical assessments and help identify patients at high risk for future disease activity[6].

New scientific evidence on Mayzent, the first and only oral treatment studied and proven to slow disability progression in a broad range of secondary progressive MS (SPMS) patients, highlight delays to disability progression and benefits in cognitive performance in patients treated with Mayzent:

- Results from EXCHANGE interim analysis showed a good safety and tolerability profile when patients switched from an oral or injectable disease-modifying therapy (DMT) to Mayzent[7].
- Further EXPAND data continue to demonstrate improvements of cognitive processing speed in patients with active and non-active SPMS treated with Mayzent[8].
- Long-term data analyses from the EXPAND trial showed sustained benefits on disability, cognitive processing speed and relapse outcomes for up to five years in patients with active SPMS treated continuously with Mayzent versus those who switched from placebo, highlighting the value of early treatment initiation[2].

New safety data on Gilenya, a cornerstone of MS treatment and the only oral DMT approved to treat relapsing forms of MS in adults and children from 10 years of age and older, were presented:

- Additional safety findings from studies on Gilenya highlight a low risk of progressive multifocal leukoencephalopathy (PML) in patients receiving Gilenya, and prevalence estimates of major congenital malformations among live births are similar to those from an untreated MS population[9,10].
- Results from the Phase IV FLUENT study, which assessed immune phenotype biomarkers in patients receiving Gilenya treatment, expand our knowledge of changes in immune cell profiles over the short and long term in RMS patients treated with Gilenya[11].

New data beyond transformative medicines on MSProDiscuss™, a first-of-its-kind clinically validated tool designed to facilitate physician–patient conversation on signs of progression in MS and to potentially allow earlier identification of patients transitioning from relapsing forms of MS to SPMS:

- Results from a large, real-world qualitative survey on MSProDiscuss™ in 34 countries showed that MSProDiscuss is a useful tool which is easy to use in patient consultations[3].

Throughout MSVirtual2020: 8th Joint ACTRIMS-ECTRIMS Meeting, Novartis will host dedicated content on Facebook, Twitter and LinkedIn.

About Multiple Sclerosis
Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system characterized by myelin destruction and axonal damage in the brain, optic nerves and spinal cord[12]. MS, which affects approximately 2.3 million people worldwide[13], can be characterized into four main types of MS: clinically isolated syndrome (CIS), relapsing remitting (RRMS), SPMS and primary progressive (PPMS)[14]. The various forms of MS can be distinguished based on whether a patient experiences relapses (clearly defined acute inflammatory attacks of worsening neurological function), and/or whether they experience progression of neurologic damage and disability from the onset of the disease[12].

Novartis in Neuroscience
Novartis has a strong ongoing commitment to neuroscience and to bringing innovative treatments to patients suffering from neurological conditions where there is a high unmet need. We are committed to supporting patients and physicians in multiple disease areas, including MS, migraine, Alzheimer's disease, Parkinson's disease, epilepsy and attention deficit hyperactivity disorder, and have a promising pipeline in MS, Alzheimer's disease, spinal muscular atrophy and specialty neurology.

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About Novartis
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 products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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Novartis Media Relations
E-mail: media.relations@novartis.com

Antonio Ligi
Novartis External Communications
+41 61 324 13 74
antonio.ligi@novartis.com

Michael Amos
Novartis Global Pharma Communications
+41 61 324 2705 (direct)
+41 79 123 7806 (mobile)
michael.amos@novartis.com

Eric Althoff
Novartis US External Communications
+1 862 778 3243
+1 646 438 4335
eric.althoff@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944

E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 778 5052
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		