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

- 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

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

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 2020⁴:

- New findings from the ASCLEPIOS Phase III trials demonstrate Kesimpta’s superior efficacy vs teriflunomide in newly diagnosed, treatment-naive patients with low absolute relapse rates, very low magnetic resonance imaging (MRI) lesion activity and prolonged time to disability worsening¹.
- 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 trials⁵.
- 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 activity⁶.

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 Mayzent⁷.
- Further EXPAND data continue to demonstrate improvements of cognitive processing speed in patients with active and non-active SPMS treated with Mayzent⁸.
- 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 initiation².

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 population⁵,¹⁰.
- 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 Gilenya¹¹.

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 consultations³.

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\textsuperscript{12}. MS, which affects approximately 2.3 million people worldwide\textsuperscript{13}, can be characterized into four main types of MS: clinically isolated syndrome (CIS), relapsing remitting (RRMS), SPMS and primary progressive (PPMS)\textsuperscript{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\textsuperscript{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.

Disclaimer
This media update contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this media update, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this media update will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission.

Novartis is providing the information in this media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update as a result of new information, future events or otherwise.

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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