NEWS RELEASE

# Merck Presents New MAVENCLAD® (Cladribine Tablets) Data Highlighting Sustained Reduction in NfLs and Benefit of Early Initiation

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- New data showed sustained reduction in neurofilament light chain (NfL) levels over two years of treatment with MAVENCLAD® (cladribine tablets) in patients with relapsing multiple sclerosis (RMS)
- Findings from real-world evidence (RWE) studies suggest a shift toward the use of cladribine tablets in treatment-naïve RMS patients with high rates of treatment continuation at four years

DARMSTADT, Germany--(BUSINESS WIRE)-- Not intended for UK and U.S. based media

Merck, a leading science and technology company, today announced the presentation of new analyses from the MAVENCLAD® (cladribine tablets) MAGNIFY-MS study, which demonstrated that patients with relapsing multiple sclerosis (RMS) experienced sustained reduction in serum neurofilament light chain (NfL), indicating that MAVENCLAD reduced neuronal injury over two years. Additional data include two real-world evidence (RWE) studies, which indicated an increase in the use of cladribine tablets in treatment-naïve patients and demonstrated low levels of switching to other disease-modifying therapies (DMTs) up to four years. These data were presented at the 9th Joint ECTRIMS-ACTRIMS meeting in Milan, Italy.

Analyses from the post-hoc MAGNIFY-MS study showed that throughout the two-year treatment course of MAVENCLAD, median serum NfL Z-scores were reduced in all patient groups compared to baseline. These findings suggest that MAVENCLAD effectively reduced neuronal injury across magnetic resonance imaging (MRI) outcome subgroups.

“Our commitment to the MS community drives our unwavering focus on generating data that provide further

insights into the efficacy and safety of MAVENCLAD," said Alexander Kulla, Senior Vice President & Medical Unit Head Neurology & Immunology at Merck. "We know that serum NfL levels are increasingly used as an important biomarker in MS, signaling possible disease activity that can lead to progression. The findings presented at ECTRIMS-ACTRIMS demonstrate that MAVENCLAD produced sustained reductions in serum NfL without continuous immunosuppression."

Two real-world studies also presented at ECTRIMS-ACTRIMS reinforce the potential benefits of initiating treatment with cladribine tablets in the earlier stages of the disease. In the five-year follow-up of the CLARENCE study, conducted in the United Kingdom, it was found that 36.1% of 2,685 assessed patients were treatment-naïve during treatment commencement. In a separate study out of Latin America, data was analyzed from 1,421 patients who received at least one course of cladribine tablets. Over time, an increasing trend in treatment initiation among treatment-naïve patients was observed, suggesting an advantage of early utilization of cladribine treatment. As well in both studies, very few patients receiving cladribine tablets switched to other therapies.

To keep up to date with our activities at ECTRIMS-ACTRIMS along with future data and information, please visit **merckneurology.com/newsroom** or follow us on Twitter @MerckHealthcare and LinkedIn: Healthcare Business of Merck. To view our abstracts & posters presented at the 9th Joint ECTRIMS-ACTRIMS meeting, please visit **https://ectrims.eu/msmilan2023-abstracts/**.

## About MAVENCLAD®

MAVENCLAD, approved by the U.S. Food and Drug Administration (FDA) on March 29, 2019, is the first and only short-course oral therapy for the treatment of adults with relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS). Because of its safety profile, use of MAVENCLAD is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of multiple sclerosis (MS), and MAVENCLAD is not recommended for use in patients with clinically isolated syndrome (CIS). Patients should follow healthcare provider instructions including cancer screening, contraception and blood tests. The approved dose of MAVENCLAD is 3.5 mg per kg body weight over two years, administered as one treatment course of 1.75 mg per kg per year, each consisting of two treatment weeks. The mechanism by which cladribine exerts its therapeutic effects in patients with multiple sclerosis has not been fully elucidated but is thought to involve cytotoxic effects on B and T lymphocytes through impairment of DNA synthesis, resulting in depletion of lymphocytes. MAVENCLAD causes a dose-dependent reduction in lymphocyte counts followed by recovery.

Because cladribine is cytotoxic, special handling and disposal instructions should be followed.

MAVENCLAD has been approved in over 80 countries, including the European Union (EU), Canada, Australia and Switzerland, for various relapsing MS indications. Visit **www.MAVENCLAD.com** for more information.

## About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common non-traumatic, disabling neurological disease in young adults. It is estimated that approximately 2.8 million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

## Merck in Neurology and Immunology

Merck has a long-standing legacy in neurology and immunology, with significant R&D and commercial experience in multiple sclerosis (MS). The company's current MS portfolio includes two products for the treatment of relapsing MS – Rebif® (interferon beta-1a) and MAVENCLAD® (cladribine tablets). Merck aims to improve the lives of patients by addressing areas of unmet medical needs. In addition to Merck's commitment to MS, the company also has a pipeline focusing on discovering new therapies that have potential in other neuroinflammatory and immune-mediated diseases, including systemic lupus erythematosus (SLE), generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD).

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## About Merck

Merck, a leading science and technology company, operates across life science, healthcare and electronics. Around 60,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2021, Merck generated sales of € 19.7 billion in 66 countries.

Scientific exploration and responsible entrepreneurship have been key to Merck's technological and scientific advances. This is how Merck has thrived since its founding in 1668. The founding family remains the majority owner of the publicly listed company. Merck holds the global rights to the Merck name and brand. The only exceptions are the United States and Canada, where the business sectors of Merck operate as EMD Serono in healthcare, MilliporeSigma in life science and EMD Electronics.

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