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Merck KGaA, Darmstadt, Germany Shares Advances in MS Portfolio with Key Efficacy and Safety Data at AAN 2022

- **New Phase II data show evobrutinib sustained low annualized relapse rates (ARRs) and had no new safety signals at 2.5 years – the longest follow-up of any Bruton's tyrosine kinase inhibitor in multiple sclerosis (MS)**
- **Updated safety data continue to demonstrate patients treated with MAVENCLAD® (cladribine) tablets for their MS who have confirmed or suspected COVID-19 had mild to moderate disease symptoms and no increased risk of serious outcomes**
- **A retrospective analysis of real-world data from the GLIMPSE study shows MAVENCLAD had lower ARRs and lower risk of relapse than fingolimod, dimethyl fumarate and teriflunomide in relapsing MS patients**

Darmstadt, Germany, March 31, 2022 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced 13 abstracts from the Company's multiple sclerosis (MS) portfolio will be presented at the 2022 American Academy of Neurology (AAN) Annual Meeting, being held April 2-7. Data being presented include presentations on investigational Bruton's tyrosine kinase (BTK) inhibitor evobrutinib, including new 2.5-year efficacy and safety data in patients with relapsing multiple sclerosis (RMS) from a Phase II open-label extension study and a Phase II post-hoc analysis demonstrating that treatment with evobrutinib led to a reduction in slowly expanding lesions (SEL), which may be associated with

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chronic inflammation in the central nervous system (CNS). Additionally, retrospective real-world efficacy and safety data on MAVENCLAD® (cladribine) tablets will be presented, including relapse data compared to other oral disease modifying therapies (DMTs) as well as COVID-19 outcomes.

"Focusing on the needs of people with MS is at the heart of everything we do. This includes innovative research with real-world data to better understand the effectiveness of MAVENCLAD in clinical practice to help inform treatment decisions," said Jan Klatt, Senior Vice President, Head of Development Unit Neurology & Immunology, Merck KGaA, Darmstadt, Germany. "Additionally, we are working tirelessly on the future of MS treatments with evobrutinib, which targets both acute and potentially also chronic inflammation to prevent disease progression and achieve better outcomes for patients. With new evobrutinib data at AAN, we now have two and a half years of efficacy and safety data in patients with relapsing MS from the largest Phase II BTK inhibitor clinical trial."

Key evobrutinib data include:

- Safety and efficacy results from the evobrutinib Phase II open-label extension, finding no new safety signals and maintained efficacy (annualized relapse rate of 0.12 for patients receiving evobrutinib 75mg twice-daily in the 48-week double-blind period) over 2.5 years in patients with RMS
- Data from a post-hoc analysis in the Phase II trial with evobrutinib demonstrating a reduction in volume of SELs, an in-vivo magnetic resonance imaging (MRI) correlate with chronic active inflammation and axonal loss within the CNS, which may be predictive of subsequent clinical disease progression in MS

Key MAVENCLAD® (cladribine) tablets data include:

- Data from the Phase IV CLARIFY-MS and MAGNIFY-MS studies demonstrating MS patients treated with MAVENCLAD who acquired COVID-19 typically experienced mild to moderate disease symptoms/effects with no increased risk of serious outcomes from COVID-19 infection

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- Data from the GLIMPSE study*, a longitudinal, retrospective analysis of adult patients identified with RMS from the MSBase Registry, showing MAVENCLAD had lower annualized relapse rates and lower risk of relapse than fingolimod, dimethyl fumarate and teriflunomide in RMS patients

Additional Company activities at AAN 2022:

- Industry Therapeutic Update 1: "Early DMT Switch Considerations in MS and Discussing the Capacity to Mount an Immune Response" chaired by Ann Bass, MD, Medical Director of the comprehensive MS clinic at the Neurology Center of San Antonio (April 2, 7-8:30 p.m. PDT, Grand Ballroom, Sheraton Grand, Seattle)
- Industry Therapeutic Update 2: "Seeing What's Unseen in MS" chaired by Jiwon Oh, MD, PhD, Medical Director, BARLO MS Centre, St. Michael's Hospital, Toronto (April 4, 7-10 p.m. PDT, Grand Ballroom, Sheraton Grand, Seattle)

In addition to the data being presented at AAN, Merck KGaA, Darmstadt, Germany launched a new educational initiative for neurologists on the potential role of BTK in MS. The initiative "BTK and MS" focuses on three key areas: the lack of control over chronic neuroinflammation for those living with MS, the challenges healthcare providers face in measuring disease progression, and the potential role of BTK in MS pathology. More information on the initiative can be found at BTKandMS.com.

To keep up to date with our activities at AAN along with future data and information, follow us on Twitter @EMDSerono and LinkedIn: EMD Serono, Inc. #AANAM #MSInsideOut

Below is the full list of Merck KGaA, Darmstadt, Germany-related abstracts accepted for presentation at AAN 2022:

Abstract Name	Authors	Presentation Details
Evobrutinib Oral Presentations:		
Effects of Evobrutinib, a Bruton's Tyrosine Kinase Inhibitor, on	Arnold D, Elliott C, Montalban X *et al.*	**Program ID:** 009

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Slowly Expanding Lesions, an Emerging Imaging Marker of Chronic Tissue Loss in Multiple Sclerosis		**Session:** S24 - MS Therapeutics **Date:** April 4, 2022 **Time:** 5:06 pm PDT/8:06 pm EDT **Presenter:** Arnold D
Safety Profile Characterization of Evobrutinib in Over 1000 Patients from Phase II Clinical Trials in Multiple Sclerosis, Rheumatoid Arthritis and Systemic Lupus Erythematosus	Montalban X, Wallace D, Genovese MC *et al.*	**Program ID:** 007 **Session:** S14 - MS Therapeutics **Date:** April 4, 2022 **Time:** 4:42 pm PDT/7:42 pm EDT **Presenter:** Montalban X
Evobrutinib Poster Presentations:		
Safety and Efficacy of Evobrutinib, a Bruton's Tyrosine Kinase Inhibitor in Relapsing Multiple Sclerosis Over 2.5 Years of the Open-label Extension to a Phase II Trial	Montalban X, Wolinsky JS, Arnold DL *et al.*	**Program ID:** 001 **Neighborhood:** 4 **Session:** P5 - MS Clinical Trials and Therapeutics 1 **Date:** April 3, 2022 **Time:** 11:45 am-12:45 pm PDT/2:45 pm-3:45 pm EDT **Presenter:** Montalban X
The Role of Human and Mouse BTK in Myeloid Cells	Bassani C, Molinari M, Martinielli V *et al*.	**Program ID:** 006 **Session:** P3 - MS Immunology and Basic Science 1 **Date:** April 2, 2022 **Time:** 5:30 pm-6:30 pm PDT/8:30 pm-9:30 pm EDT **Presenter:** Muzio L
MAVENCLAD® (cladribine) tablets Poster Presentations:		
Clinical Outcomes in Patients With COVID-19 During Two Phase IV Studies of Cladribine Tablets for Treatment of Multiple Sclerosis: An Update	Yavorskaya V, Karan R, Borsi L *et al.*	**Program ID:** 005 **Neighborhood:** 4 **Session:** P11 - MS COVID 2 **Date:** April 5, 2022 **Time:** 11:45 am-12:45 pm PDT/2:45 pm-3:45 pm EDT **Presenter:** Salloukh H

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Real-world Comparative Effectiveness and Persistence of Cladribine Tablets and Other Oral Disease-modifying Treatments for Multiple Sclerosis from GLIMPSE: Results from the MSBase Registry	Butzkueven H, Spelman T, Ozakbas S *et al.*	**Program ID:** 003 **Neighborhood:** 4 **Session:** P12 - MS Clinical Practice & Decision Making 4 **Date:** April 5, 2022 **Time:** 5:30 pm-6:30 pm PDT/8:30 pm-9:30 pm EDT **Presenter:** Verdun Di Cantogno E
Comparative Effectiveness of Cladribine versus Fingolimod in the Treatment of Highly Active Relapsing Multiple Sclerosis: The MERLYN (MavEnclad Real worLd comparative efficacy Non-iNterventional) Study	Brownlee W, Haghikia A, Hayward B *et al.*	**Program ID:** 005 **Neighborhood:** 4 **Session:** P7 - MS Clinical Trials & Therapeutics 3 **Date:** April 4, 2022 **Time:** 8:00 am-9:00 am PDT/11:00 am-12:00 pm EDT **Presenter:** Brownlee W
Cladribine Tablets In Patients With Relapsing Remitting Multiple Sclerosis Or Active Secondary Progressive Multiple Sclerosis After Suboptimal Response To A Disease Modifying Therapy (CLICK-MS and MASTER-2): Interim Baseline And Safety Review	Aldridge J, Bass A, Evans E *et al.*	**Date:** April 24-27, 2022 **Virtual e-Poster Presenting:** Miravalle A
Rebif® (interferon beta-1a) subcutaneous injection Poster Presentations:		
Exploratory Analysis of Serum GDF-15 Levels in Patients Receiving Subcutaneous Interferon β-1a in the REFLEX Trial	Coray M, Seitzinger A, Roy S *et al.*	**Program ID:** 007 **Neighborhood:** 4 **Session:** P2 - MS Biomarkers **Date:** April 2, 2022 **Time:** 11:45 am-12:45 pm PDT/2:45 pm-3:45 pm EDT **Presenter:** Verdun di Cantogno E
Post-approval Safety of Subcutaneous Interferon B-1a in the Treatment of Multiple Sclerosis, With Particular	Freedman MS, Todorović M, Murgašová Z *et al.*	**Program ID:** 005 **Neighborhood:** 4

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Reference to Respiratory Viral Infections		**Session:** P8 - MS Therapeutics MOA and Safety 3 **Date:** April 4, 2022 **Time:** 11:45 am-12:45 pm PDT/2:45 pm-3:45 pm EDT **Presenter:** Korick J
INFORM - Interferon beta Exposure in the 2nd and 3rd Trimester of Pregnancy a – Register-Based Drug Utilisation Study in Finland and Sweden	Sabidó M, Suzart Woischnik K, Grimes N *et al.*	**Program ID:** 009 **Neighborhood:** 4 **Session:** P8 - MS Special Populations 2 **Date:** April 4, 2022 **Time:** 11:45 am-12:45 pm PDT/2:45 pm-3:45 pm EDT **Presenter:** Verdun de Cantogno E
Non-Product Specific Poster Presentations:		
Patient Practices and Experiences During COVID-19 Among Individuals Enrolled in MS LifeLines Patient Support Program	Costantino H, Lebson L, Mackie dMS *et al.*	**Date:** April 24-27, 2022 **Virtual e-Poster Presenting:** Nicholas J
A Cross-Sectional Survey Evaluating Cladribine Tablets Treatment Patterns Among Patients with Multiple Sclerosis Enrolled in the MS LifeLines Patient Support Program	Nicholas J, Mackie dMS, Castantino H *et al.*	**Date:** April 24-27, 2022 **Virtual e-Poster Presenting:** Nicholas J

*Previously presented at ACTRIMS 2022

About Evobrutinib
Evobrutinib (M2951) is an oral, highly selective inhibitor of Bruton's tyrosine kinase (BTK) in clinical development as a potential treatment for multiple sclerosis (MS). It is the first BTK inhibitor to demonstrate clinical efficacy in the largest Phase II study with follow-up beyond two years as well as demonstrate an impact on early biomarkers of chronic inflammation that correlate with disease progression. Evobrutinib is designed to inhibit primary B cell responses such as proliferation and antibody and cytokine release, without directly affecting T cells. Evobrutinib is currently under clinical investigation and not approved for any use anywhere in the world.

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.

IMPORTANT SAFETY INFORMATION

WARNING: MALIGNANCIES and RISK OF TERATOGENICITY

- **Treatment with MAVENCLAD may increase the risk of malignancy. MAVENCLAD is contraindicated in patients with current malignancy. In patients with prior malignancy or with increased risk of malignancy, evaluate the benefits and risks of the use of MAVENCLAD on an individual patient basis. Follow standard cancer screening guidelines in patients treated with MAVENCLAD**
- **MAVENCLAD is contraindicated for use in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception because of the potential for fetal harm. Malformations and embryolethality occurred in animals. Exclude pregnancy before the start of treatment with MAVENCLAD in females of reproductive potential. Advise females and males of reproductive potential to use effective contraception during MAVENCLAD dosing and for 6 months after the last dose in each treatment course. Stop MAVENCLAD if the patient becomes pregnant**

CONTRAINDICATIONS

- Patients with current malignancy.
- Pregnant women, and women and men of reproductive potential who do not plan to use effective contraception during and for 6 months after the last dose in each treatment course. May cause fetal harm.
- Patients with human immunodeficiency virus (HIV).
- Patients with active chronic infections (e.g., hepatitis or tuberculosis).
- Patients with a history of hypersensitivity to cladribine.

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- Women intending to breastfeed while taking MAVENCLAD tablets and for 10 days after the last dose.

WARNINGS AND PRECAUTIONS

- **Malignancies:** Treatment with MAVENCLAD may increase the risk of malignancy. After the completion of 2 treatment courses, do not administer additional MAVENCLAD treatment during the next 2 years. In clinical studies, patients who received additional MAVENCLAD treatment within 2 years after the first 2 treatment courses had an increased incidence of malignancy. The risk of malignancy with reinitiating MAVENCLAD more than 2 years after the completion of 2 treatment courses has not been studied. Follow standard cancer screening guidelines in patients treated with MAVENCLAD.
- **Risk of Teratogenicity:** MAVENCLAD may cause fetal harm when administered to pregnant women. In females of reproductive potential, exclude pregnancy before initiation of each treatment course of MAVENCLAD and prevent by the use of effective contraception during MAVENCLAD dosing and for at least 6 months after the last dose of each treatment course. Women who become pregnant during treatment with MAVENCLAD should discontinue treatment.
- **Lymphopenia:** MAVENCLAD causes a dose-dependent reduction in lymphocyte count. In clinical studies, 87% of MAVENCLAD-treated patients experienced lymphopenia. The lowest absolute lymphocyte counts occurred approximately 2 to 3 months after the start of each treatment course and were lower with each additional treatment course. Concomitant use of MAVENCLAD with hematotoxic drugs may increase the risk of adverse reactions because of the additive hematological effects. Monitor lymphocyte counts before and during treatment, periodically thereafter, and when clinically indicated.
- **Infections:** MAVENCLAD can reduce the body's immune defense and may increase the likelihood of infections. Infections occurred in 49% of MAVENCLAD-treated patients compared to 44% of patients treated with placebo in clinical studies. The most frequent serious infections included herpes zoster and pyelonephritis. Single fatal cases of tuberculosis and fulminant hepatitis B were reported in the clinical program. Administer live-attenuated or live vaccines at least 4 to 6 weeks prior to starting MAVENCLAD. Screen patients for latent infections; consider delaying treatment until infection is fully controlled. Vaccinate patients antibody-negative to varicella zoster virus prior to treatment. Administer anti-herpes prophylaxis in patients with lymphocyte counts less than 200 cells per microliter. Monitor for infections. In patients treated with parenteral cladribine for oncologic indications, cases of progressive multifocal leukoencephalopathy (PML) have been reported. No case of PML has been reported in clinical studies of cladribine in patients with MS.
- **Hematologic Toxicity:** In addition to lymphopenia, decreases in other blood cells and hematological parameters have been reported with MAVENCLAD in clinical studies. In general, mild to moderate decreases in neutrophil counts, hemoglobin levels, and platelet counts were observed. Severe decreases in neutrophil counts were observed in 3.6% of MAVENCLAD-treated patients, compared to 2.8% of placebo patients. Obtain

complete blood count (CBC) with differential including lymphocyte count before and during treatment, periodically thereafter, and when clinically indicated.

- **Risk of Graft-versus-Host Disease With Blood Transfusions:** Transfusion-associated graft-versus-host disease has been observed rarely after transfusion of nonirradiated blood in patients treated with cladribine for non-MS treatment indications.
- **Liver Injury:** In clinical studies, 0.3% of MAVENCLAD-treated patients had liver injury (serious or causing treatment discontinuation) compared to 0 placebo patients. Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels prior to treatment. Discontinue if clinically significant injury is suspected.
- **Hypersensitivity:** In clinical studies, 11% of MAVENCLAD-treated patients had hypersensitivity reactions, compared to 7% of placebo patients. Hypersensitivity reactions that were serious and/or led to discontinuation of MAVENCLAD, occurred in 0.5% of MAVENCLAD-treated patients, compared to 0.1% of placebo patients. If a hypersensitivity reaction is suspected, discontinue MAVENCLAD therapy. Do not use MAVENCLAD in patients with a history of hypersensitivity to cladribine.
- **Cardiac Failure:** In clinical studies, one MAVENCLAD-treated patient experienced life-threatening acute cardiac failure with myocarditis, which improved after approximately one week. Cases of cardiac failure have also been reported with parenteral cladribine used for treatment indications other than multiple sclerosis.

Adverse Reactions: The most common adverse reactions with an incidence of >20% for MAVENCLAD are upper respiratory tract infection, headache, and lymphopenia.

Drug Interactions/Concomitant Medication: Concomitant use of MAVENCLAD with immunosuppressive or myelosuppressive drugs and some immunomodulatory drugs (e.g., interferon beta) is not recommended and may increase the risk of adverse reactions. Acute short-term therapy with corticosteroids can be administered.

Avoid concomitant use of certain antiviral and antiretroviral drugs. Avoid concomitant use of BCRP or ENT/CNT inhibitors as they may alter bioavailability of MAVENCLAD.

Use in Specific Populations: Studies have not been performed in pediatric or elderly patients, pregnant or breastfeeding women. Use in patients with moderate to severe renal or hepatic impairment is not recommended.

Please see the full **Prescribing Information**, including **boxed WARNING** for additional information.

About Rebif® (interferon beta-1a)
Rebif (interferon beta-1a) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting

disease, and active secondary progressive disease, in adults. It is used to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS.

IMPORTANT SAFETY INFORMATION:
Rebif is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, human albumin, or any other component of the formulation.

Rebif should be used with caution in patients with depression, a condition that is common in people with multiple sclerosis. Depression, suicidal ideation, and suicide attempts have been reported to occur with increased frequency in patients receiving interferon compounds, including Rebif.

Severe liver injury, including some cases of hepatic failure requiring liver transplantation, has been reported rarely in patients taking Rebif. The potential for liver injury should be considered when used in combination with other products associated with liver injury. Monitor liver function tests and patients for signs and symptoms of hepatic injury. Consider discontinuing Rebif if hepatic injury occurs.

Anaphylaxis and other allergic reactions (some severe) have been reported as a rare complication of Rebif. Discontinue Rebif if anaphylaxis occurs.

In controlled clinical trials, injection site reactions occurred more frequently in Rebif-treated patients than in placebo-treated and Avonex-treated patients. Injection site reactions including injection site pain, erythema, edema, cellulitis, abscess, and necrosis have been reported in the postmarketing setting. Do not administer Rebif into affected area until fully healed; if multiple lesions occur, discontinue Rebif until skin lesions are healed.

Decreased peripheral blood counts in all cell lines, including pancytopenia, have been reported in Rebif-treated patients. In controlled clinical trials, leukopenia occurred at a higher frequency in Rebif-treated patients than in placebo and Avonex-treated patients. Thrombocytopenia and anemia occurred more frequently in 44 mcg Rebif-treated patients than in placebo-treated patients. Patients should be monitored for symptoms or signs of decreased blood counts. Monitoring of complete blood and differential white blood cell counts is also recommended.

Cases of thrombotic microangiopathy (TMA), some fatal, have been reported with interferon beta products, including Rebif, up to several weeks or years after starting therapy. Discontinue Rebif if clinical symptoms and laboratory findings consistent with TMA occur, and manage as clinically indicated.

Caution should be exercised when administering Rebif to patients with pre-existing seizure disorders. Seizures have been temporally associated with the use of beta interferons, including Rebif, in clinical trials and in postmarketing reports.

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The most common side effects with Rebif are injection-site disorders, headaches, influenza-like symptoms, abdominal pain, depression, elevated liver enzymes, and hematologic abnormalities.

Epidemiological data do not suggest a clear relationship between interferon beta use and major congenital malformations, but interferon beta may cause fetal harm based on animal studies. Data from a large human population-based cohort study, as well as other published studies over several decades, have not identified a drug-associated risk of major birth defects with interferon beta products during early pregnancy. Findings regarding a potential risk for low birth weight or miscarriage with the use of interferon beta products in pregnancy have been inconsistent.

Please see the full Prescribing Information for additional information: https://www.emdserono.com/us-en/pi/rebif-pi.pdf

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 KGaA, Darmstadt, Germany in Neurology and Immunology
Merck KGaA, Darmstadt, Germany 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 KGaA, Darmstadt, Germany aims to improve the lives of patients by addressing areas of unmet medical needs. In addition to Merck KGaA, Darmstadt, Germany'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 KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science 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 advancing gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2021, Merck KGaA, Darmstadt, Germany, generated sales of € 19.7 billion in 66 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.