

News Release

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Merck KGaA, Darmstadt, Germany, Announces Positive Phase IIB Results for Evobrutinib in Relapsing Multiple Sclerosis

- Primary endpoint met for evobrutinib (Bruton's Tyrosine Kinase Inhibitor - BTK) in relapsing multiple sclerosis (MS)
- First proof of concept for BTK inhibitor in MS

Darmstadt, Germany, March 7, 2018 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced positive results from its Phase IIb study of evobrutinib (Bruton's Tyrosine Kinase Inhibitor – BTK) in relapsing multiple sclerosis (MS). The study has met its primary endpoint, demonstrating that evobrutinib resulted in a clinically meaningful reduction of gadolinium enhancing T1 lesions measured at weeks 12, 16, 20 and 24 in comparison to patients receiving placebo.

"We are encouraged by these early positive results of evobrutinib in relapsing MS," says Luciano Rossetti, Head of Global Research & Development at the Biopharma business of Merck KGaA, Darmstadt, Germany. "The trial will continue so as to further inform our clinical development strategy for evobrutinib in MS."

Details on this clinical study can be found on <u>ClinicalTrials.gov</u>.

Evobrutinib, discovered by Merck KGaA, Darmstadt, Germany, is also in Phase IIb studies in rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE).



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About evobrutinib

Evobrutinib (M2951) is in clinical development to investigate its potential as a treatment for multiple sclerosis (MS), rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE). It is an oral, highly selective inhibitor of Bruton's Tyrosine Kinase (BTK) which is important in the development and functioning of various immune cells including B lymphocytes and macrophages. Evobrutinib is designed to inhibit primary B cell responses such as proliferation and antibody and cytokine release, without directly affecting T cells. BTK inhibition is thought to suppress autoantibody-producing cells, which preclinical research suggests may be therapeutically useful in certain autoimmune diseases. Evobrutinib is currently under clinical investigation and not approved for any use anywhere in the world.

Merck KGaA, Darmstadt, Germany, in Immunology

Merck KGaA, Darmstadt, Germany, has a long-standing legacy in immunology, with significant R&D and commercial experience in multiple sclerosis. Our robust immunology pipeline focuses on discovering new therapies that have the potential to modulate key pathogenic mechanisms in chronic diseases such as MS, systemic lupus erythematosus (SLE) and forms of arthritis, including rheumatoid arthritis (RA) and osteoarthritis (OA).

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries. Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the *"Merck KGaA, Darmstadt, Germany"* name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.