

News Release

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Merck KGaA, Darmstadt, Germany, Advances Immunology Pipeline with Evobrutinib (Bruton's Tyrosine Kinase Inhibitor)

- **Phase IIa signal finding trial of evobrutinib in rheumatoid arthritis patients progresses to Phase IIb**
- **Patient enrollment completed significantly ahead of schedule in multiple sclerosis trial**
- **One of the broadest clinical programs of a BTK inhibitor in multiple autoimmune disorders underway with three Phase II clinical trials**

Darmstadt, Germany, September 12, 2017 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that it is continuing to advance its Immunology pipeline.

Evobrutinib, a Bruton's Tyrosine Kinase Inhibitor (BTKi) discovered by Merck KGaA, Darmstadt, Germany, is now in Phase IIb studies across multiple immunological indications: rheumatoid arthritis (RA), multiple sclerosis (MS), and systemic lupus erythematosus (SLE).

"Our strategic aim in Immunology is to deliver best-in-disease treatment options to patients with high unmet medical needs," says Luciano Rossetti, Head of Global R&D for the biopharma business of Merck KGaA, Darmstadt, Germany. "Our broad clinical



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trial program for evobrutinib in multiple immune-mediated disorders underscores our belief in its potential for patients living with chronic diseases.”

In RA, Merck KGaA, Darmstadt, Germany, recently initiated a Phase IIb study after results from a small Phase IIa signal-generating study (n=65) met the pre-defined criteria for progressing to a dose finding study. The purpose of this signal study was to characterize the role of evobrutinib in patients with a broad range of disease activity. The study did not reach the statistical criteria across all patients enrolled, however, there was a clear positive outcome in the pre-specified patient population conventionally studied across RA pivotal trials, which is the population to be enrolled in the Phase IIb dose-finding study. Full results of the Phase IIa trial will be presented at a future scientific meeting.

In multiple sclerosis, the Phase II clinical trial is evaluating the safety and effectiveness of evobrutinib in patients with relapsing remitting MS. Patients have been placed into one of five groups, receiving evobrutinib at one of three different dose levels, placebo or dimethyl fumarate, for 24 weeks. After 24 weeks, the patients on placebo will be given evobrutinib. Patient enrollment is now complete, with Merck KGaA, Darmstadt, Germany, achieving its goal of enrolling 250 patients across 55 sites six months ahead of schedule.

Merck KGaA, Darmstadt, Germany's, Phase II systemic lupus erythematosus study is on schedule to read out in Q4 2019.

Merck KGaA, Darmstadt, Germany, is evaluating strategic partnerships and financing for evobrutinib in order to realize the full potential of the program.

Merck KGaA, Darmstadt, Germany, is also investigating another proprietary BTK inhibitor in oncology: M7583 is currently being evaluated in a Phase I clinical trial for hematological malignancies.

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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. Merck KGaA, Darmstadt, Germany, has a robust immunology pipeline focused 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“ name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.