

News Release

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Merck KGaA, Darmstadt, Germany Announces First Patient Dosed in Phase III Study of Oral Cladribine in Generalized Myasthenia Gravis (gMG)

- **MyClad is a global Phase III study evaluating the efficacy and safety of cladribine capsules for the treatment of generalized Myasthenia Gravis (gMG)**
- **Cladribine capsules have the potential to be the first oral treatment for gMG patients**
- **gMG is a rare, chronic autoimmune neuromuscular disorder that results in muscle weakness in the eyes, mouth, throat, and limbs**

Darmstadt, Germany [AUGUST 29, 2024] – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced the first patient has been dosed in the Phase III MyClad trial ([NCT06463587](https://clinicaltrials.gov/ct2/show/study/NCT06463587)) evaluating the efficacy and safety of oral cladribine for the treatment of generalized Myasthenia Gravis (gMG). Cladribine capsules have the potential to be the first oral treatment for gMG patients. gMG is a rare, neuromuscular disorder causing muscle weakness that can be severe and have a significant impact on patients' lives.

Cladribine is expected to selectively target B and T lymphocytes. These cells are thought to be the root cause of gMG through the production of the harmful autoantibodies that drive inflammation at the connection points between nerves and muscles. This mechanism of action coupled with a short course oral dosing taken at

home may ultimately slow the progression of the disease by targeting its underlying cause while diminishing treatment burden.

“Given our extensive experience in addressing patients’ needs in immune-driven neurological conditions, we believe that cladribine capsules represent a highly differentiated potential therapeutic option for gMG,” said Jan Klatt, Head of Development Unit Neurology & Immunology for the Healthcare business of Merck KGaA, Darmstadt, Germany. “This treatment approach holds the promise of achieving a high degree of disease activity control, offering greatly improved convenience, and ultimately enabling patients to live their lives as normally as possible.”

MyClad is a global Phase III, randomized, double-blind and placebo-controlled study designed to assess the efficacy and safety of cladribine capsules in 240 patients with gMG.

About generalized Myasthenia Gravis

Generalized Myasthenia Gravis (gMG) is a rare, chronic autoimmune neuromuscular disorder characterized by muscle weakness and fatigue, impacting an estimated 700,000 people worldwide. The disease can strike anyone at any age but is more frequently seen in young women (age 20 to 30) and men aged 50 and older. In gMG, the communication between the nerves and the muscles, particularly at the neuromuscular junction (NMJ), is disrupted causing muscle weakness. This can result in the loss of control in the eye muscles and a variable combination of the arms, legs, and respiratory muscles. The unpredictable severity and frequency of symptoms in gMG patients can be debilitating, significantly impacting various aspects of day-to-day life.

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), cutaneous lupus erythematosus (CLE) and generalized myasthenia gravis (gMG).

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across life science, healthcare and electronics. Around 63,000 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 2023, Merck KGaA, Darmstadt, Germany, generated sales of €21 billion in 65 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 MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in 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.

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