

News Release

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Merck KGaA, Darmstadt, Germany Takes Patient-Directed Approach to Bring Innovation to the Treatment of Rare Neuromuscular Disorder, Generalized Myasthenia Gravis

- **Cladribine capsules have the potential to be the first oral treatment for people living with rare, chronic autoimmune neuromuscular disorder, generalized Myasthenia Gravis**
- **Cladribine capsules has received Fast Track designation and Orphan Drug Designation by the US FDA**
- **Company has established an MG patient council to provide insights on how to best meet the needs of patients in the gMG rare disease community**

Darmstadt, Germany, November 24, 2025 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for cladribine capsules for the treatment of the rare, chronic autoimmune neuromuscular disorder, generalized Myasthenia Gravis (gMG). In June 2023, the FDA granted Orphan Drug Designation for cladribine capsules for the treatment of gMG. In addition, the Company is actively collaborating with patient organizations and Ad Scientiam, a medical technology company, to support a patient-directed approach to the future management of gMG.



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If approved, cladribine capsules, currently being studied in the global Phase 3 MyClad trial, could become the first oral treatment for gMG, a rare autoimmune neuromuscular disorder that causes severe muscle weakness and significantly impacts patients' lives. The FDA's Fast Track program is designed to facilitate the development and accelerate the review of therapies for serious conditions with unmet medical needs, potentially bringing treatments to patients sooner. The FDA Orphan Drug Designation is designed to encourage the development of treatments for rare diseases or conditions, often defined as those affecting fewer than 200,000 patients in the U.S.

"The FDA's Fast Track designation, together with Orphan Drug Designation, affirms that more treatments are needed for the gMG community," said David Weinreich, MD, Global Head of R&D and Chief Medical Officer for the Healthcare business of Merck KGaA, Darmstadt, Germany. "As a patient-directed company, we are prioritizing the voices of MG patients in shaping our clinical program. Their insights will continue to be instrumental to ensure we meet the needs of patients to deliver therapeutic innovation for this rare, chronic autoimmune neuromuscular disorder."

To shape the MyClad trial and ensure it meets the needs of patients, Merck KGaA, Darmstadt, Germany developed a patient council and collaborates with more than 20 MG patient advocacy groups around the world. Insights from the council have informed study protocols, recruitment materials and potential future product packaging options for the clinical trial program.

In addition, [the company is collaborating with Ad Scientiam](#), a medical equipment manufacturing company, to launch a prospective, multi-center pilot study exploring an investigational software as a medical device designed to support the management of people living with gMG. The study will investigate how wearable technologies, smartphone-based functional tests, and electronic patient-reported outcomes (ePROs) could detect changes in disease trajectory in real-world conditions.

The MyClad trial ([NCT06463587](#)) is a global Phase 3, randomized, double-blind and placebo-controlled study designed to assess the efficacy and safety of cladribine

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capsules in 264 patients with gMG. Cladribine is proposed to target selectively the B and T cells believed to contribute to the production of harmful autoantibodies that cause inflammation and damage to the neuromuscular junction. This mechanism of action, combined with a short-course infrequently-administered oral regimen taken at home, that if approved, may help reduce the burden of the disease by addressing its underlying cause.

Merck KGaA, Darmstadt, Germany will announce results from the MyClad trial following its completion and remains committed to ongoing collaboration with the gMG community to ensure patient needs continue to guide clinical developments.

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.

About the MyClad Phase 3 Clinical Trial Program

The MyClad trial (NCT06463587) is a global Phase 3, randomized, double-blind and placebo-controlled study designed to assess the efficacy and safety of cladribine capsules in 264 patients with gMG. In the study patients will be randomized to receive either two short courses of cladribine (low-dose or high-dose) or matched oral placebo, with courses separated by 4 weeks, followed by a blinded extension period and a retreatment period to assess sustained benefit, need for retreatment and long-term safety. The primary endpoint is change from baseline in the MG-Activities of Daily Living (MG-ADL) score at Week 24 of the double-blind placebo-controlled period.

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across life science, healthcare and electronics. More than 62,000 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 2024, Merck KGaA, Darmstadt, Germany, generated sales of € 21.2 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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