UCB News

UCB to unveil new data for RYSTIGGO®▼ and ZILBRYSQ®▼ for gMG at the 2025 AANEM Annual Meeting and MGFA Scientific Session

- UCB will showcase 18 abstracts, including an oral presentation, demonstrating continued commitment to advancing targeted treatments for generalized myasthenia gravis (gMG).
- Presentations include new post hoc analyses considering corticosteroid dose tapering during treatment with RYSTIGGO®▼ (rozanolixizumab)[1] and the impact of ZILBRYSQ®▼ (zilucoplan) on Myasthenia Gravis Quality of Life 15-revised (MG-QoL15r) items.[2]

Brussels (Belgium), 29 Oct 2025, 07:00 (CET) UCB (Euronext Brussels: UCB), a global biopharmaceutical company, today announced that it will be presenting new data highlighting insights on patient outcomes with rozanolixizumab and zilucoplan for the treatment of generalized Myasthenia Gravis (gMG) at the 2025 American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting and Myasthenia Gravis Foundation of America (MGFA) Scientific Session, taking place between October 29 – November 1, 2025, San Francisco, USA.

A total of 18 abstracts will be presented at AANEM and the MGFA scientific session, highlighting UCB's dedication to driving advancements in gMG treatment. These presentations will cover data on rozanolixizumab and zilucoplan, including new insights on corticosteroid-sparing strategies and quality of life improvements, and long-term safety and effectiveness data. Additionally, insights from a real-world study on user characteristics and adherence patterns from the HumaMG app will be shared, reinforcing UCB's commitment to improving gMG management.

"Empowering patients with innovative solutions is at the core our purpose at UCB," said Donatello Crocetta, Global Head of Medical Affairs & Chief Medical Officer at UCB. "Our presentations at the AANEM Annual Meeting and MGFA Scientific Session showcase our focus on developing treatment options that not only highlight clinical management but also quality of life, providing meaningful outcomes that make a difference for those living with gMG."

"At UCB, we are deeply proud to present a robust range of data at this year's AANEM Annual Meeting and MGFA Scientific Session, demonstrating our commitment to elevating the lives of patients with gMG through shared decision-making and continuous collaboration with healthcare professionals," added Kimberly, Moran, PhD, MBA, SVP & Head, US Rare Diseases. "People living with gMG face unpredictable symptoms that can greatly impact their ability to perform daily activities. Expanding the body of evidence generation of the risks and benefits of our gMG targeted therapies is central to our mission of delivering meaningful, sustainable clinical improvements to address the unique challenges these patients encounter."

Key UCB scientific and real-world data to be presented at AANEM and the MGFA Scientific Session include:

- An oral presentation focusing on data from the double-blind Phase 3 MycarinG study and its open-label extensions (OLE) including a comprehensive analysis of corticosteroid dose tapering during treatment with rozanolixizumab in patients with gMG.[1]
- A new and comprehensive analysis of treatment response from the Phase 3 MycarinG study and its open-label extensions offering valuable information on efficacy of rozanolixizumab in a clinical setting.[3]
- Data from a further analysis of the Phase 3 MycarinG study explores the long-term safety of cyclic rozanolixizumab treatment in patients with generalized Myasthenia Gravis (gMG) to evaluate its potential for sustained therapeutic use.[4]

Inspired by patients.
Driven by science.

- Post hoc data from the Phase 3 RAISE-XT trial examining zilucoplan's impact on health-related quality-of-life items, including more severe ones such as difficulty speaking.[2]
- New data on the long-term effectiveness of zilucoplan, focusing on severe exacerbations in gMG based on predictive modeling from the Phase 3 RAISE and RAISE-XT clinical trial and a U.S. real-world database.[5]
- From the RAISE-XT 120-week follow-up, new post-hoc data looking at the long-term effect of zilucoplan treatment on fatigue.[6]
- An analysis exploring user characteristics and adherence patterns among individuals living with Myasthenia Gravis (MG), leveraging data from the HumaMG app to provide valuable real-world insights into patient management and engagement.[7]

UCB is also hosting a panel discussion entitled 'Continuing the Conversation - Subpopulations with Barriers to Care in Myasthenia Gravis' on October 29, 2025. There will also be a UCB-sponsored Industry Therapeutic Update on expert perspectives on two targeted generalized myasthenia gravis treatments on October 31, 2025.

Faces of MG

To further shine a light on MG, UCB is collaborating with the MG community on the recently launched 'Faces of MG' campaign, seeking to elevate the voices of those deeply connected to the disease and to foster understanding of the invisible impact it has on people's lives. Learn more: **https://www.ucb.com/solutions/diseases/myasthenia-gravis/faces-of-MG.**

UCB presentations during AANEM and MGFA Scientific Session 2025

Lead author	Abstract title	Presentation Details
Pascuzzi R	Corticosteroid dose tapering during treatment with rozanolixizumab in patients with gMG: post hoc analysis	MGFA SS (Oral session C)
Vu T	Response to rozanolixizumab in patients with gMG: Final pooled analysis of MycarinG and open-label extension studies	AANEM session I & II and MGFA SS (Poster)
Habib AA	Long-term safety of cyclic rozanolixizumab treatment in patients with gMG: a final analysis of phase 3 studies	AANEM session I & III and MGFA SS (Poster)
Barnett-Tapia C	Measuring the effect of rozanolixizumab treatment in the MycarinG study using the Myasthenia Gravis Impairment Index	AANEM session I & II and MGFA SS (Poster)
Vu T	Rozanolixizumab treatment patterns in patients with gMG: a post hoc analysis of final pooled phase 3 data	MGFA SS (Poster)
Park M	Characteristics of patients with gMG initiating rozanolixizumab treatment in the United States	MGFA SS (Poster)
Habib AA	Repeated cycles of rozanolixizumab treatment in patients with anti-MuSK antibody-positive gMG	MGFA SS (Poster)
Gandhi-Mehta RK	Manual push administration of rozanolixizumab in gMG	MGFA SS (Poster)
Gandhi-Mehta RK	Patient preferences and experience with self-administration of rozanolixizumab in gMG: The MG0020 study	AANEM session I & II (Poster)
Gandhi-Mehta RK	Self-administration of rozanolixizumab in patients with gMG: The MG0020 study	AANEM session I & II (Poster)

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Weiss MD	Interpreting patient quality-of-life experience with zilucoplan treatment in gMG in RAISE and RAISE-XT	MGFA SS (Poster)
Weiss MD	Effect of zilucoplan on fatigue in patients with gMG: RAISE-XT 120-week follow-up	AANEM session I & III and MGFA SS (Poster)
Freimer M	The long-term effectiveness of zilucoplan in MG: predictive modeling in a US real-world database	AANEM session I & II and MGFA SS (Poster)
Freimer M	Zilucoplan treatment of severe exacerbations leading to hospitalization in gMG: study design	MGFA SS (Poster)
Howard JF	Sustained minimal symptom expression in generalized myasthenia gravis: A 120-week post hoc analysis of RAISE-XT	AANEM session I & II (Poster)
Freimer M	Switching to SC zilucoplan from IV complement component 5 inhibitors in MG: patient preference and satisfaction from a Phase 3B study	AANEM session I & III (Poster)
Perrin-Ross A	Educational needs assessment of nurses involved in the care of patients with MG	AANEM session I & II and MGFA SS (Poster)
Aral M	Real-world insights from people living with MG: Analysis of user characteristics and adherence patterns from the HumaMG app	MGFA SS (Poster)

For further information, contact UCB:

Global Communications
Nick Francis
T: +44 7769 307745
nick.francis@ucb.com

Rare Disease Communications
Daphne Teo
T +1 (770) 880-7655
daphne.teo@ucb.com

Corporate Communications, Media Relations
Laurent Schots
T +32.2.559.92.64
Laurent.schots@ucb.com

Investor Relations
Antje Witte
T +32.2.559.94.14
antje.witte@ucb.com

About generalized myasthenia gravis (gMG)
gMG is a rare autoimmune disease with a global prevalence of 100–350 cases per 1 million people.[8] People living with gMG can experience a variety of symptoms, including severe muscular weakness that can result in

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double vision, drooping eyelids, difficulty with swallowing, chewing and talking, as well as life-threatening weakness of the muscles of respiration.[9,10]

In gMG, pathogenic autoantibodies can impair synaptic transmission at the neuromuscular junction (NMJ) by targeting specific proteins on the post-synaptic membrane.[11] This disrupts the ability of the nerves to stimulate the skeletal muscle and results in a weaker contraction.[9,10] gMG can occur in any race, gender or age. [9,10]

About rozanolixizumab

- Rozanolixizumab 140 mg/ml solution for injection is a subcutaneously administered, humanized monoclonal antibody that specifically binds, with high affinity, to human neonatal Fc receptor (FcRn). It has been designed to block the interaction of FcRn and Immunoglobulin G (IgG), accelerating the catabolism of antibodies and reducing the concentration of pathogenic IgG autoantibodies.[12]
- In June 2023, rozanolixizumab-noli was approved by the FDA, for the treatment of gMG in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody-positive, having been granted Priority Review for its Biologic License Application (BLA).[13]
- In September 2023, rozanolixizumab was granted approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of generalized myasthenia gravis (gMG) in adult patients (only for patients who inadequately respond to steroids or other immunosuppressants).[14]
- In January 2024, the European Commission granted approval of RYSTIGGO® (rozanolixizumab) as an add-on to standard therapy for the treatment of generalized Myasthenia Gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody-positive.[15]

About zilucoplan

- Zilucoplan is a once-daily SC injection, self-administered peptide inhibitor of complement component 5 (C5 inhibitor).[16]
- As the only self-administered C5 inhibitor targeted therapy for gMG, zilucoplan may inhibit complement-mediated damage to the neuromuscular junction through its targeted mechanism of action.[16]
- In September 2023, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved zilucoplan for the treatment of gMG in adult patients (only for patients who inadequately respond to steroids or other immunosuppressants).[17]
- In October 2023, zilucoplan was approved by the U.S. Food and Drug Administration (FDA) for the treatment of gMG in adult patients who are anti-acetylcholine receptor (AchR) antibody positive.[16]
- In December 2023, the European Commission granted zilucoplan approval as an add-on to standard therapy for the treatment of generalized Myasthenia Gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody-positive.[18]
- Orphan designation was granted by the FDA in 2019 to zilucoplan for the treatment of myasthenia gravis.[19]

About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With approximately 9,000 people in approximately 40 countries, the company generated revenue of € 6.15 billion in 2024. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

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Forward-looking statements

This press release may contain forward-looking statements including, without limitation, statements containing the words "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: the global spread and impact of COVID-19, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, will progress to product approval or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products, which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB's efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

UCB is providing this information, including forward-looking statements, only as of the date of this press release and it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated

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otherwise. UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. UCB expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.

Important Safety Information about RYSTIGGO® (rozanolixizumab-noli) in the US[13]
RYSTIGGO (rozanolixizumab-noli) is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.[13]

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS
Infections: RYSTIGGO may increase the risk of infection. Delay RYSTIGGO administration in patients with an active infection until the infection is resolved. During treatment with RYSTIGGO, monitor for clinical signs and symptoms of infection. If serious infection occurs, administer appropriate treatment and consider withholding RYSTIGGO until the infection has resolved.

Immunization
Immunization with vaccines during RYSTIGGO treatment has not been studied. The safety of immunization with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because RYSTIGGO causes a reduction in IgG levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with RYSTIGGO. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with RYSTIGGO.

Aseptic Meningitis: Serious adverse reactions of aseptic meningitis (also called drug-induced aseptic meningitis) have been reported in patients treated with RYSTIGGO. If symptoms consistent with aseptic meningitis develop, diagnostic workup and treatment should be initiated according to the standard of care.

Hypersensitivity Reactions: Hypersensitivity reactions, including angioedema and rash, were observed in patients treated with RYSTIGGO. Management of hypersensitivity reactions depends on the type and severity of the reaction. Monitor patients during treatment with RYSTIGGO and for 15 minutes after for clinical signs and symptoms of hypersensitivity reactions. If a reaction occurs, institute appropriate measures if needed.

ADVERSE REACTIONS
In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of RYSTIGGO-treated patients) were headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea. Serious infections were reported in 4% of patients treated with RYSTIGGO. Three fatal cases of pneumonia were identified, caused by COVID-19 infection in two patients and an unknown pathogen in one patient. Six cases of infections led to discontinuation of RYSTIGGO.

Please refer to the full Prescribing Information for additional Important Safety Information.

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Important Safety Information about ZILBRYSQ® (zilucoplan) in the US[16]

ZILBRYSQ is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.[16]

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS
ZILBRYSQ, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis*. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of ZILBRYSQ, unless the risks of delaying therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccination against meningococcal bacteria in patients receiving a complement inhibitor.**
- **Patients receiving ZILBRYSQ are at increased risk for invasive disease caused by N*eisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ZILBRYSQ REMS.

CONTRAINDICATIONS
ZILBRYSQ is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.
WARNINGS AND PRECAUTIONS
Serious Meningococcal Infections
ZILBRYSQ, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors. The initiation of ZILBRYSQ treatment is contraindicated in patients with unresolved serious Neisseria meningitidis infection.

Complete or update meningococcal vaccination (for serogroups A, C, W, Y and B) at least 2 weeks prior to administration of the first dose of ZILBRYSQ, according to current ACIP recommendations for patients receiving a complement inhibitor.

If urgent ZILBRYSQ therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Consider interruption of ZILBRYSQ in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated.

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ZILBRYSQ REMS
Due to the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a REMS called ZILBRYSQ REMS.

Under the ZILBRYSQ REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risk of serious meningococcal infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccines. Additional information on the REMS requirements is available at www.ZILBRYSQREMS.com or 1-877-414-8353.

Other Infections
Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported in patients treated with complement inhibitors. ZILBRYSQ blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Administer vaccinations for the prevention of *Streptococcus pneumoniae* infection according to ACIP recommendations. Patients receiving ZILBRYSQ are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

Pancreatitis and Other Pancreatic Conditions
Pancreatitis and pancreatic cysts have been reported in patients treated with ZILBRYSQ. Patients should be informed of this risk before starting ZILBRYSQ. Obtain lipase and amylase levels at baseline before starting treatment with ZILBRYSQ. Discontinue ZILBRYSQ in patients with suspected pancreatitis and initiate appropriate management until pancreatitis is ruled out or has resolved.

ADVERSE REACTIONS
In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of gMG patients treated with *ZILBRYSQ*) were injection site reactions, upper respiratory tract infections, and diarrhea.

Please refer to the full Prescribing Information for additional Important Safety Information.

Important Safety Information about RYSTIGGO® (rozanolixizumab) in the EU/EEA*[15]

RYSTIGGO®▼ (rozanolixizumab) EU/EEA* Important Safety Information
▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.*

The most commonly reported adverse reactions were headache (48.4%), diarrhoea (25.0%) and pyrexia (12.5%). The adverse reactions from clinical studies and post-marketing experience in gMG are as follows: Very common (≥1/10) headache, diarrhoea, and pyrexia; Common (≥1/100 to <1/10) upper respiratory tract infections including cases of nasopharyngitis, rash, angioedema, arthralgia, nausea, vomiting and injection site reactions; Not known, herpes viral infection (includes cases of Herpes Zoster, simplex and oral), aseptic meningitis. In MG0003, headache was the most common reaction reported in 31 (48.4%) and 13 (19.4%) of the patients treated with rozanolixizumab and placebo, respectively. All headaches, except 1 (1.6%) severe headache, were either mild (28.1% [n=18]) or moderate (18.8% [n=12]) and there was no increase in incidences of headache with repeated cyclic treatment.

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Rozanolixizumab is contra-indicated in patients with hypersensitivity to the active substance or to any of the excipients.

Treatment with rozanolixizumab in patients with impending or manifest myasthenic crisis has not been studied. Aseptic meningitis (drug induced aseptic meningitis) has been reported following rozanolixizumab treatment. If symptoms consistent with aseptic meningitis (headache, pyrexia, neck stiffness, nausea, vomiting) occur, diagnostic workup and treatment should be initiated as per standard of care.

As rozanolixizumab causes transient reduction in IgG levels the risk of infections may increase. Overall, in phase 3 studies in gMG, infections were reported in 45.2 % of all rozanolixizumab treated patients. No increase in the incidence of infections was observed from cycle to cycle. Serious infections were reported in 4.3 % of patients. Treatment with rozanolixizumab should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. During treatment with rozanolixizumab, clinical signs and symptoms of infections should be monitored. If a clinically important active infection occurs, withholding rozanolixizumab until the infection has resolved should be considered.

Infusion reactions such as rash or angioedema may occur. In the clinical trial, these were mild to moderate. Patients should be monitored during treatment with rozanolixizumab and for 15 minutes after the administration is complete for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, rozanolixizumab infusion should be discontinued and appropriate measures should be initiated if needed. Once resolved, administration may be resumed.

Immunisation with vaccines during rozanolixizumab therapy has not been studied. The safety of immunisation with live or live-attenuated vaccines and the response to immunisation with vaccines are unknown. All vaccines should be administered according to immunisation guidelines and at least 4 weeks before initiation of treatment. For patients that are on treatment, vaccination with live or live-attenuated vaccines is not recommended. For all other vaccines, they should take place at least 2 weeks after the last infusion of a treatment cycle and 4 weeks before initiating the next cycle.

This medicinal product contains 29 mg of proline in each ml. The use in patients suffering from hyperprolinaemia should be restricted to cases where no alternative treatment is available. This medicinal product contains 0.3 mg of polysorbate 80 in each ml. Polysorbates may cause allergic reactions.

Please consult the full prescribing information in relation to other side effects, full safety profile and product information. https://www.ema.europa.eu/en/documents/product-information/rystiggo-epar-product-information_en.pdf

Date of last revision: 18th September 2025

*EU is an abbreviation for the European Union. EEA is an abbreviation for the European Economic Area.

ZILBRYSQ®▼ (zilucoplan) EU/EEA* Important Safety Information[18]

▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.*

The most frequently reported adverse reactions were injection site reactions (injection site bruising (13.9%) and injection site pain (7.0%)) and upper respiratory tract infections (nasopharyngitis (5.2%),

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upper respiratory tract infection (3.5%) and sinusitis (3.5%)). The adverse reactions from the pooled placebo-controlled (n=115) and open-label extension (n=213) studies in gMG are as follows: Very common adverse reactions: (≥ 1/10): Upper respiratory tract infections and Injection site reactions; Common adverse reactions (≥ 1/100 to < 1/10): Diarrhoea, Lipase increased, Amylase increased and Morphoea; Uncommon adverse reaction ((≥ 1/1000 to < 1/100) blood eosinophils increased. Zilucoplan is contra-indicated in patients with hypersensitivity to the active substance or to any of the excipients, in patients who are not currently vaccinated against Neisseria meningitidis and in patients with unresolved Neisseria meningitidis infection. Due to its mechanism of action, the use of zilucoplan may increase the patient's susceptibility to infections with Neisseria meningitidis. As a precautionary measure, all patients must be vaccinated against meningococcal infections, at least 2 weeks prior to the start of treatment. If treatment needs to start less than 2 weeks after vaccination against meningococcal infections, the patient must receive appropriate prophylactic antibiotic treatment until 2 weeks after the first vaccination dose. Meningococcal vaccines reduce but do not completely eliminate the risk of meningococcal infections. Vaccines against serogroups A, C, Y, W, and where available, serogroup B, are recommended for preventing the commonly pathogenic meningococcal serogroups. Vaccination and prophylactic antibiotic treatment should occur according to most current relevant guidelines. During treatment, patients should be monitored for signs and symptoms of meningococcal infection and evaluated immediately if infection is suspected. In case of a suspected meningococcal infection, appropriate measures such as treatment with antibiotics and discontinuation of treatment, should be taken until the meningococcal infection can be ruled out. Patients should be instructed to seek immediate medical advice if signs or symptoms of meningococcal infections occur. Prescribers should be familiar with the educational materials for the management of meningococcal infections and provide a patient alert card and patient/carer guide to patients treated with zilucoplan. In addition to Neisseria meningitidis, patients treated with zilucoplan may also be susceptible to infections with other Neisseria species, such as gonococcal infections. Patients should be informed on the importance of gonorrhea prevention and treatment. Prior to initiating zilucoplan therapy, it is recommended that patients initiate immunizations according to current immunization guidelines.

Please consult the full product information in relation to other side effects, full safety profile and prescribing information. https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf Date of last revision: 28 April 2025.

**EU/EEA means European Union/European Economic Area.*

References:

[1] Pascuzzi R, et al. 2025. Corticosteroid dose tapering during treatment with rozanolixizumab in patients with gMG: post hoc analysis. Oral presentation (Wednesday Session C) 110 at: MGFA Scientific Session at The American Academy of Neurology and Electrodiagnostic Medicine Annual Meeting (AANEM). 2025 October 29-31; California, USA.
[2] Weiss, MD, et al. Interpreting patient quality-of-life experience with zilucoplan treatment in gMG in RAISE and RAISE-XT. Poster presented at: MGFA Scientific Session at The American Academy of Neurology and Electrodiagnostic Medicine Annual Meeting (AANEM). 2025 October 29-31; California, USA.

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[3] Vu T, et al. Response to rozanolixizumab in patients with gMG: Final pooled analysis of MycarinG and open-label extension studies. Poster presented at: MGFA Scientific Session at The American Academy of Neurology and Electrodiagnostic Medicine Annual Meeting (AANEM); 2025 October 29-31; California, USA.
[4] Habib AA, et al. Long-term safety of cyclic rozanolixizumab treatment in patients with gMG: a final analysis of phase 3 studies. Poster presented at: MGFA Scientific Session at The American Academy of Neurology and Electrodiagnostic Medicine Annual Meeting (AANEM); 2025 October 29-31; California, USA.
[5] Freimer M, et al. The long-term effectiveness of zilucoplan in MG: predictive modeling in a US real-world database. Poster presented at: MGFA Scientific Session at The American Academy of Neurology and Electrodiagnostic Medicine Annual Meeting (AANEM); 2025 October 29-31; California, USA.
[6] Weiss, MD, et al. Effect of zilucoplan on fatigue in patients with gMG: RAISE-XT 120-week follow-up. Poster presented at: MGFA Scientific Session at The American Academy of Neurology and Electrodiagnostic Medicine Annual Meeting (AANEM); 2025 October 29-31; California, USA.
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