UCB News

UCB presents latest data from its targeted generalized myasthenia gravis treatment portfolio at International Congress on Neuromuscular Diseases 2026

- **Long-term rozanolixizumab treatment cycles showed repeated and consistent benefit across ocular and wider generalized myasthenia gravis (gMG) symptoms:** Final pooled data from the Phase 3 MycarinG study and its open-label extension studies showed improvements across ocular signs and symptoms, alongside consistent benefits in bulbar, respiratory and limb weakness/gross motor function in adults living with gMG compared with placebo[1,2]
- **Repeated rozanolixizumab cycles showed consistent benefit in MuSK Ab+ gMG:** Final pooled data from the Phase 3 MycarinG study and its open-label extension studies showed consistent improvements from baseline in MG-ADL and QMG scores across adult patients with MuSK antibody-positive (MuSK Ab+) gMG[3]
- **Usability of zilucoplan pre-filled pen:** A usability study supports appropriate and effective use of the zilucoplan pre-filled pen in gMG, with 90% of adult participants, including injection-naïve patients and caregivers, successfully injecting on their first untrained attempt[4]
- **Long-term treatment with zilucoplan provided sustained benefit across a broad range of signs and symptoms of gMG:** Improvements or no symptoms were observed in a greater proportion of adult patients across individual items in MG-specific outcomes at Week 12 versus placebo, and were sustained through to Week 120[5]

Brussels (Belgium) 8 July 2026, 7:00 (CEST) – UCB (Euronext Brussels: UCB), a global biopharmaceutical company, is presenting new data at the International Congress on Neuromuscular Diseases (ICNMD) 2026 (7-11 July) indicating that long-term, symptom-driven rozanolixizumab cycles improved ocular symptoms in generalized myasthenia gravis (gMG) and produced consistent benefit across the broader signs and symptoms of gMG in adult patients compared with placebo. Additionally, long-term treatment with zilucoplan was associated with sustained benefit across a broad range of signs and symptoms of gMG in adults living with the condition.[5] Data from a human factors validation study support appropriate and effective use[4] of the newly approved zilucoplan pre-filled pen, the first once-daily subcutaneous C5 inhibitor available as a pre-filled pen in Europe.[6] In total, 11 abstracts are being presented by UCB across the meeting.

These data underscore UCB's approach to addressing the heterogeneity of gMG with a portfolio of two targeted treatment options designed to support individual patient needs and preferences.

"People living with gMG experience a significant symptom burden, from vision-related symptoms such as eyelid drooping and double-vision to challenges with speaking, swallowing, mobility, and everyday independence," said Donatello Crocetta, Global Head of Medical Affairs & Chief Medical Officer at UCB. "Understanding this variability and building a fuller picture of how we can support people in managing their symptoms is central to how we partner with the gMG community and tailor treatment approaches to individual needs."

Long-term rozanolixizumab cycles led to improvements across ocular items in MG-specific outcome measures[1]

A post hoc pooled analysis of final data from the Phase 3 MycarinG study (NCT03971422) and open-label extensions MG0004 (NCT04124965) and MG0007 (NCT04650854) evaluated repeated, symptom-driven rozanolixizumab cycles on ocular item scores in adults living with gMG. Among 129 patients who received ≥2

GL-RZ-2600063 Date of preparation: July 2026

symptom-driven cycles, weighted-mean ocular item scores were assessed at baseline and Day 43 across Cycles 1–13.

- Improvements were seen consistently across clinician- and patient- reported measures for double vision and ptosis (eyelid drooping).
- Eye-related quality-of-life impact also improved, with adult patients with gMG reporting a reduction in trouble using their eyes.
- Overall, the findings suggested long-term benefit of repeated, symptom-driven rozanolixizumab cycles for ocular signs and symptoms in adults living with gMG.
- In total, 93.1% (n=175/188) of patients with ≥1 treatment cycle across MycarinG and MG0007 experienced a TEAE; most were mild or moderate.

Consistent improvements were observed across MG-ADL and QMG item scores with long-term rozanolixizumab[2]

A second post hoc analysis of the final pooled MycarinG, MG0004 and MG0007 datasets assessed individual item-level scores within the Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) total scores at baseline and Day 43, across 13 treatment cycles, in 129 adult gMG patients with ≥2 symptom-driven cycles receiving rozanolixizumab.*

- MG-ADL improvements were observed for double vision, eyelid droop, talking and chewing, and swallowing.
- QMG improvements were also seen for double vision, ptosis, facial muscles, speech, and upper- and lower-limb strength items.
- Overall, the findings suggest consistent benefit of long-term rozanolixizumab cycles across ocular, bulbar, respiratory, and limb weakness/gross motor symptoms in adult patients with gMG.
- In total, 93.1% (n=175/188) of patients experienced a TEAE; most were mild or moderate;
    - The most common TEAEs were headache (50.0%; n=94/188), diarrhoea (33.5%; n=63/188) and COVID-19 (21.8%; n=41/188).
    - The incidence of TEAEs did not increase with repeated cyclic treatment.

* Rozanolixizumab doses 7 mg/kg or 10 mg/kg were used during these symptom driven cycles. 10 mg/kg is not a licensed dose of rozanolixizumab in the EU. The EU approval of rozanolixizumab is based on data from the ≈7 mg/kg dose group

Consistent symptom control across repeated rozanolixizumab cycles in MuSK Ab+ adult patients with gMG[3]

Final pooled data from MycarinG and its open-label extensions, MG0004 and MG0007, observed the effect of repeated symptom-driven rozanolixizumab treatment in 12 adult patients with MuSK antibody-positive (MuSK Ab+) gMG, with outcomes tracked across up to 13 cycles.

- Patient-reported symptom burden improved, with weighted-mean MG-ADL scores shifting from 10.4 at baseline to 5.2 at Day 43 across 13 repeated cycles.
- Weighted-mean QMG scores also improved, from 16.8 at baseline to 9.4 at Day 43 across 13 cycles.
- Findings indicate consistent clinical benefit with an acceptable safety profile for rozanolixizumab in adult patients with MuSK Ab+ gMG.
- In patients with MuSK Ab+ gMG and ≥1 treatment cycle (n=18), 14 (77.8%) reported treatment-emergent adverse events (TEAEs); most TEAEs were mild or moderate.

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Human factors validation study supports usability of the zilucoplan pre-filled pen[4]
A study of 100 adult participants, including injection-experienced and injection-naïve patients with gMG (or surrogate patients with ocular symptoms), injection-experienced and injection-naïve caregivers (or caregivers of surrogate patients), and healthcare professionals, assessed use-related safety and effectiveness of the newly approved zilucoplan pre-filled pen.[6] The button-free pen, which contains a pre-filled syringe enclosed within it so that the needle is not visible, is intended to make self-administration easier for people living with gMG.

- Without prior training, 90% (n=90/100) of participants performed a successful injection (defined as holding the pre-filled pen against the skin until the injection is complete) with the pre-filled pen on their first attempt.
- Observed use errors did not introduce new risks.
- Minor changes were made to the Instructions for Use to address relevant errors identified in simulated-use tasks or knowledge-based questions.
- Data support that the zilucoplan pre-filled pen is appropriate and effective for use in adult patients with gMG, with no new hazards or use-related risks identified, reinforcing the pre-filled pen as an additional self-administration option that may suit different preferences and circumstances.

The zilucoplan pre-filled pen recently received a positive opinion from the CHMP as a new additional device presentation to be used as an add-on to standard therapy for the treatment of adults living with gMG who are anti-acetylcholine receptor (AChR) antibody positive.[6]

Long-term zilucoplan treatment provided sustained benefit across broad range of gMG signs and symptoms[5]
A post hoc analysis of the Phase 3 RAISE study and its ongoing open-label extension, RAISE-XT, evaluated item-level changes in disease-specific outcomes among adults with anti-acetylcholine receptor antibody-positive (AChR Ab+) gMG. The analysis assessed symptom changes across individual items of the MG-ADL, QMG, and MG Quality of Life 15-item revised (MG-QoL15r) scales from baseline to Week 12 in RAISE and through Week 120 in RAISE-XT.

- At Week 12 in RAISE, a greater proportion of patients receiving zilucoplan (n=84) had improvement or no symptoms across all MG-ADL items versus placebo (n=73), including chewing (71.4% vs 49.4%), talking (73.8% vs 57.6%), eyelid droop (65.5% vs 48.2%), and rising from chairs (63.1% vs 43.5%).
- Improvements increased further and were sustained through Week 120 in RAISE-XT, with high proportions of patients receiving zilucoplan (n=73) reporting improvement or no symptoms across MG-ADL items, including chewing and talking (both 93.2%), swallowing and brushing hair/teeth (both 87.7%), and eyelid droop (86.3%).
- Similar results were observed for QMG and MG-QoL15r.
- These data show that long-term treatment with zilucoplan may provide benefit across a broad range of signs and symptoms of gMG.

Clarity is Critical: UCB gMG Symposium
UCB will also host an interactive symposium at the Congress bringing together expert clinicians to explore the key patient factors influencing treatment decisions in gMG, using a case-based, audience-driven format informed by the latest clinical evidence and real-world experience. The symposium will take place on Wednesday, 8 July, 13:15 – 14:15 CEST.

UCB News

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Forward-looking statements

This document contains forward-looking statements, including, without limitation, statements containing the words "potential", "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 guaranteeing 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 be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document.

Important factors that could result in such differences include but are not limited to: global spread and impacts of wars, pandemics and terrorism, the general geopolitical environment, climate change, 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, supply chain disruption and business continuity risks; 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 or disruptive technologies/business models, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring, retention and compliance of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, 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

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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 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, the public is cautioned not to place any undue reliance on such forward-looking statements. These forward-looking statements are made only as of the date of this document, and do not reflect any potential impacts from the evolving event or risk as mentioned above as well as any other adversity, unless indicated otherwise. The company continues to follow the development diligently to assess the financial significance of these events, as the case may be, to UCB.

UCB expressly disclaims any obligation to update any forward-looking statements in this document, 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.

RYSTIGGO®▼ (rozanolixizumab) EU/EEA* Important Safety Information[7]

▼*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.*

Rystiggo is authorized 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.

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.

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: 16th January 2026

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

ZILBRYSQ®▼ (zilucoplan) EU/EEA Important Safety Information[8]**

▼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.

Zilbrysq is indicated 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 in three approved doses: 16.6, 23 and 32.4 mg.

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%), 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): Diarrhea, 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 SmPC.

Date of last revision: 19 March 2026.

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

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GL-RZ-2600063