UCB News

UCB data presented at 2026 AANEM Annual Meeting and MGFA Scientific Session underscore leadership in advancing targeted treatments for gMG

- **Analyses of achievement of minimal symptom expression in generalized myasthenia gravis (gMG) patients receiving either ZILBRYSQ®▼ (zilucoplan) or RYSTIGGO®▼ (rozanolixizumab) treatment**: 120-week post hoc analysis of Phase 3 RAISE-XT open-label extension for zilucoplan and Phase 3 MycarinG study for rozanolixizumab and its open-label extensions[1,2]
- **Underrecognized perspectives of people living with ocular MG and ocular symptoms of gMG**: Study reports significant functional, emotional, and socioeconomic impact, and limited access to specialized and multidisciplinary care[3]
- **Traditional socioeconomic status indicators fail to identify risks in Black gMG patients:** Research found that CORE-5, a 5-item social risk screening tool, (housing, food security, transportation, utilities, and safety) may identify clinically relevant patient needs not captured by traditional indicators[4]
- **Safety and efficacy results of cizutamig, an investigational B-cell maturation antigen x cluster of differentiation 3 (BCMA×CD3) T-cell engager**: Interim results from a Phase 1b open-label, dose-escalation and dose-expansion study in MG[5*]

Brussels (Belgium) 29 September 2026, 7:00 (CEST) – UCB (Euronext Brussels: UCB), a global biopharmaceutical company, will present a breadth of data from its innovative myasthenia gravis portfolio at the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Congress Annual Meeting and the Myasthenia Gravis Foundation of America (MGFA) Scientific Session in Orlando, Florida, 29 September to 2 October 2026. Abstracts at AANEM and MGFA will highlight real-world and clinical data demonstrating UCB's targeted treatment portfolio for generalized myasthenia gravis (gMG).

New data include a focus on minimal symptom expression (MSE) as an increasingly important treatment goal, the burden and persistent unmet needs of those living with ocular MG and ocular symptoms of gMG, and insights into why harmful social risks relevant to neuromuscular health outcomes may persist for black patients with gMG, despite high socioeconomic resources.[1,2,3,4] In addition, early clinical data will be presented on cizutamig, an investigational BCMA×CD3 T-cell engager.[5*]

Highlights of key data presentations at AANEM and MGFA

Assessment of minimal symptom expression (MSE)[1,2]

UCB will share findings from post hoc analyses on achieving MSE in gMG including:

- Double-blind baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) scores in adult gMG patients stratified by MSE achievement (MG-ADL score of 0 or 1, without rescue therapy), being treated with zilucoplan up to Week 120 and time to MSE after initiating zilucoplan.[1]
- The proportion of patients with MSE at any time during treatment with rozanolixizumab or observation in a symptom-driven cycle up to Cycle 13, based on Cycle 1 MSE achievement.[2]

"People living with MG face a broad range of challenges that can profoundly affect them," said James F Howard Jr, Professor of Neurology and Medicine at University of North Carolina at Chapel Hill. "Assessing treatment outcomes such as MSE over time helps us better understand what meaningful disease control looks like for our patients. These insights can guide treatment decisions and support efforts to improve the day-to-day lives of people living with MG."

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Significant functional, emotional, and socioeconomic impacts of ocular myasthenia gravis (oMG), exacerbated by limited access to specialized and multidisciplinary care[3]
Mixed-methods study included an online questionnaire assessing symptom burden, diagnostic journey, and expectations regarding trial participation, and a semi-structured focus group with 10 MG/oMG patient experts representing recognized patient organizations from 10 countries.

- Study found that ocular MG imposes a substantial and multifaceted burden that affects independence, daily functioning, and emotional wellbeing.
- Visual symptoms impaired driving, digital device use, and work productivity, leading to loss of independence, social isolation, and safety risks at home, including during childcare and cooking.
- Patients strongly favored steroid-sparing therapies, improved symptom control, and prevention of progression to generalized MG.
- Incorporation of patient perspectives can help to better align clinical management and research priorities.

CORE-5 screening identified clinically meaningful risks not captured by traditional socioeconomic status (SES) indicators for black patients with generalized myasthenia gravis (gMG)[4]
207 participants with gMG completed a 70-item survey, with 16 participants selected for 1:1 semi-structured interviews:

- The study sample exceeded national averages relative to educational attainment, income, and health insurance for black adults residing in the United States.
- Despite being highly resourced across traditional domains used to measure social determinants of health, mean CORE-5 (housing, food security, transportation, utilities, and safety) scores indicated unmet social risks, with safety concerns emerging as the most prominent domain.
- Incorporation of CORE-5 screening during neuromuscular evaluation and management visits may support more inclusive, patient-centered care and justify higher-level billing codes.

"Within the diverse MG community, there may be patient groups whose unique experiences and challenges have not always been fully understood," said Donatello Crocetta, Global Head of Medical Affairs & Chief Medical Officer at UCB. "By continuing to generate meaningful data and insights, we can address these knowledge gaps and advance our understanding of MG, ensuring that progress in research and care benefits the broadest possible range of people and supports a more informed and inclusive approach to treatment."

Cizutamig* – an investigational BCMA×CD3 T-cell engager (TCE)
Interim data from a Phase 1b dose-escalation and dose-expansion study of cizutamig, an investigational BCMA×CD3 T-cell engager, will be presented. Cizutamig is designed to reduce autoantibodies by depleting B cells, plasma cells, and plasmablasts, while aiming to minimize cytokine release syndrome (CRS).[5] Cizutamig was acquired by UCB through its acquisition of Candid Therapeutics.[6]

*The safety and efficacy of cizutamig have not been established, and it is not approved by the U.S. Food and Drug Administration (FDA) or by any health authority.

Industry Therapeutic Update
In addition to its scientific presentations, UCB will host an Industry Therapeutic Update (ITU) session and hold two presentation stages on advancing understanding of treatment considerations in generalized myasthenia gravis.

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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 more than 9000 people in approximately 40 countries, the company generated revenue of €7.7 billion in 2025. UCB is listed on Euronext Brussels (symbol: UCB).

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.

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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 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.

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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%), diarrhea (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, diarrhea, 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.

Immunization with vaccines during rozanolixizumab therapy has not been studied. The safety of immunization with live or live-attenuated vaccines and the response to immunization with vaccines are unknown. All vaccines should be administered according to immunization 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.

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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.

Important Safety Information about RYSTIGGO® (rozanolixizumab-noli) in the US[8]

INDICATION

RYSTIGGO (rozanolixizumab-noli) is 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.

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.

The full Prescribing Information is available at https://www.ucb-usa.com/RYSTIGGO-prescribing-information.pdf

ZILBRYSQ®▼ (zilucoplan) EU/EEA Important Safety Information[9]**

▼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 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.

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): 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 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 prescribing information in relation to other side effects, full safety and prescribing information. Zilbrysq, INN-zilucoplan (europa.eu) *Date of last revision: 09 July 2026.*

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

Important Safety Information about ZILBRYSQ® (zilucoplan) in the U.S.[10]

INDICATION: ZILBRYSQ is a prescription medicine used to treat generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody positive.

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 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 *Neisseria 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.

ZILBRYSQ is available only through a restricted program called ZILBRYSQ REMS.

CONTRAINDICATIONS
ZILBRYSQ is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS
Other Infections
Use caution when administering ZILBRYSQ to patients with any other systemic infection.

Pancreatitis And Other Pancreatic Conditions
Pancreatitis and pancreatic cysts have been reported in patients treated with ZILBRYSQ. Discontinue ZILBRYSQ in patients with suspected pancreatitis and initiate appropriate management until pancreatitis is ruled out or has resolved.

ADVERSE REACTIONS
The most common adverse reactions (≥10%) were injection site reactions, upper respiratory tract infection, and diarrhea.

Please see the full Prescribing Information for additional Important Safety Information.

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2. Pascuzzi R, et al. Minimal symptom expression in myasthenia gravis: A post hoc analysis of Phase 3 rozanolixizumab studies. Presented at: AANEM Annual Meeting (Presentation #386) and MGFA Scientific Session (Poster #94); 29 September – 2 October 2026; Orlando, FL.
3. Kole A, et al. Living with ocular symptoms of myasthenia gravis: Patient insights. Presented at: AANEM Annual Meeting (Presentation #322); 29 September – 2 October 2026; Orlando, FL.
4. Thompson J, et al. Beyond income, education, and insurance coverage: The utility of CORE-5 social risk screening in neuromuscular practice for black patients with generalized myasthenia gravis. Presented at: AANEM Annual Meeting (Presentation #269); 29 September –2 October 2026; Orlando, FL.
5. Zhao C, et al. Safety and Efficacy of Cizutamig, a B-Cell Maturation Antigen (BCMA)×CD3 T-Cell Engager, in Generalized Myasthenia Gravis: Interim Data from a Phase 1b Dose-Escalation Study. Presented at: AANEM Annual Meeting (Presentation #39); 29 September – 2 October 2026; Orlando, FL.
6. UCB. UCB completes acquisition of Candid Therapeutics, strengthening next generation immunology pipeline. https://www.ucb.com/newsroom/press-releases/article/ucb-completes-acquisition-of-candid-therapeutics-strengthening-next-generation-immunology-pipeline. Accessed September 2026.
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