UCB News

UCB to present new data from its neurology portfolio at the 11th European Academy of Neurology (EAN) Congress 2025

- Presentations demonstrate UCB's ongoing commitment to improving outcomes for people living with neurological conditions, including epilepsies and generalized myasthenia gravis (gMG).
- New research highlights the impact of the company's two distinct targeted therapies for generalized Myasthenia gravis - RYSTIGGO®▼ (rozanolixizumab)[1] and ZILBRYSQ®▼ (zilucoplan)[2] - including long term efficacy and safety data.
- New real-world research from a European subgroup analysis examines the characteristics and outcomes of people living with prolonged epileptic seizures.

Brussels (Belgium) 20 June 2025 – 06:30 PM (CET) – UCB, a global biopharmaceutical company, today announced it will present six abstracts from its neurology portfolio at this year's Congress of the European Academy of Neurology (EAN) in Helsinki, Finland, June 21-24, 2025. The abstracts include new data and analyses with significance for people living with epilepsies and generalized myasthenia gravis (gMG).

"Our presentations at EAN 2025 deliver insights for people with epilepsy and gMG," said Donatello Crocetta, Chief Medical Officer and Head of Global Medical Affairs, UCB. "By focusing on innovative strategies designed to meet the unmet needs of those living with severe neurological conditions and integrating the perspectives of patients, our research strives to offer real improvements in outcomes and experiences."

Data to be presented at EAN include:

- **Three post hoc analyses of the RAISE-XT phase 3, open-label extension study of zilucoplan:** data evaluating the durability of minimal symptom expression up to 120 weeks in people living with gMG using zilucoplan.[3] An analysis of the effect of zilucoplan up to 120 weeks on Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) Subdomain scores which provides detailed insights into therapeutic impact across a broad range of gMG symptoms.[4] A third abstract from the study explores the effect of long term zilucoplan treatment on rescue use.[5]
- **Quality of life and long term safety data for rozanolixizumab:** pooled OLE data from MycarinG and MG0007 exploring the long-term safety of rozanolixizumab up to 13 treatment cycles,[6] and data from MycarinG study focusing on the quality of life in patients with gMG treated with rozanolixizumab[7] both providing crucial data on patient experiences and treatment impact.
- **Real-World Epilepsy Study:** a comprehensive, point-in-time survey assessing outcomes of prolonged seizures in 1,411 patients on stable anti-seizure medication regimens providing insightful data on the need for rapid and early seizure termination to avoid harmful outcomes.[8]

Symposia

- **Shaping generalised myasthenia gravis care:** addressing patient challenges and optimise outcomes: June 21, 14:15-15:15

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Lead Author	Abstract Title
gMG	
Vissing J, et al.	Long-term safety of rozanolixizumab treatment cycles in patients with generalised myasthenia gravis
Sacconi S, et al.	Quality of life in patients with generalised myasthenia gravis receiving rozanolixizumab: *Post hoc* analysis of MycarinG
Maniaol A, et al.	Improvement in myasthenia gravis-specific outcome subdomain scores with zilucoplan: RAISE-XT 120-week *post hoc* analysis
Leite I, et al.	Effect of zilucoplan on rescue therapy use in patients with generalised myasthenia gravis: RAISE-XT *post hoc* analysis
Hewamadduma C, et al.	Sustained minimal symptom expression in generalised myasthenia gravis: A 120-week *post hoc* analysis of RAISE-XT
Epilepsy	
Trinka E, et al.	Describing Patients with Prolonged Seizures: European Subgroup Results from a Global Real-World Point-In-Time Study

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About generalized myasthenia gravis (gMG)
gMG is a rare autoimmune disease with a global prevalence of 100–350 cases per every 1 million people.[9] People living with gMG can experience a variety of symptoms, including severe muscular weakness that can result in double vision, drooping eyelids, difficulty with swallowing, chewing and talking, as well as life-threatening weakness of the muscles of respiration.[10,11]

In gMG, pathogenic autoantibodies can impair synaptic transmission at the neuromuscular junction (NMJ) by targeting specific proteins on the post-synaptic membrane.[12] This disrupts the ability of the nerves to stimulate the skeletal muscle and results in a weaker contraction. gMG can occur in any race, gender or age.[10,11]

About rozanolixizumab

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- 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.[13]
- 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).[14]
- 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).[15]
- 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.[1]

About zilucoplan

- Zilucoplan is a once-daily SC, self-administered peptide inhibitor of complement component 5 (C5 inhibitor).[2]
- 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.[2]
- 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).[15]
- 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.[2]
- Orphan designation was granted by the FDA in 2019 to zilucoplan for the treatment of myasthenia gravis.[17]

About RAISE study, MycarinG study, and MG0007 study

RAISE (NCT04115293) was a multi-centre, Phase 3, randomized, double-blind, placebo-controlled study to confirm the efficacy, safety profile, and tolerability of zilucoplan in adult patients with anti-acetylcholine receptor (AChR) antibody positive gMG. Patients were randomized in a 1:1 ratio to receive daily subcutaneous (SC) injections of 0.3 mg/kg zilucoplan or placebo for 12 weeks.The primary endpoint for the RAISE study was change from baseline to Week 12 in the Myasthenia Gravis-Activities of Daily Living (MG-ADL) score. Secondary endpoints included change from baseline in the Quantitative Myasthenia Gravis (QMG) score, the Myasthenia Gravis Composite (MGC) and the Myasthenia Gravis Quality of Life 15 revised (MG-QoL15r) score to Week 12, time to first rescue therapy, the proportion of patients with minimal symptom expression (MSE) (defined as MG-ADL of 0 or 1 without rescue therapy), the proportion with a ≥3-point reduction in MG-ADL without rescue therapy and the proportion with a ≥5-point reduction in QMG without rescue therapy, all measured at Week 12. The secondary safety endpoint was incidence of TEAEs. A clinically meaningful

Date of preparation: June 2025 GL-RZ-2500033

improvement from baseline was defined as a change of − 3.5, and clinically meaningful worsening was defined as a change of + 3.2, in Neuro-QoL Short Form Fatigue T-score from double-blind baseline.[18]

The MycarinG study (NCT03971422) is a multi-center, Phase 3, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of rozanolixizumab in adult patients with gMG, with an open-label extension. The primary endpoint for the MycarinG study is change in the Myasthenia Gravis-Activities of Daily Living (MG-ADL) score, an eight-item patient-reported scale developed to assess MG symptoms and their effects on daily activities. Additional endpoints include changes in the Myasthenia Gravis composite (MG-C) score, the Quantitative MG (QMG) score, patient-reported outcomes at Day 43 and adverse events (AEs). The majority of patients taking part in the MycarinG study opted to enroll in any future extensions to this clinical trial. As a result, UCB is exploring the potential for further extension studies into this treatment.[13]

After MycarinG, two additional studies (MG0004 and MG0007) were started to confirm whether rozanolixizumab continues to be effective and safe over long-term treatment of MG. In MG0004, patients were treated with rozanolixizumab every week for up to 52 weeks. After MG0004 was started, MG0007 was set up to assess repeated 6-week treatment cycles of rozanolixizumab, with more cycles given only if a patient's symptoms worsened after they finished a rozanolixizumab treatment cycle. Once MG0007 was open, patients could move from MG0004 to MG0007 or enter MG0007 directly from MycarinG. Repeated 6-week treatment cycles of rozanolixizumab in 127 patients over approximately a year demonstrated a consistent improvement in the severity of MG symptoms across multiple treatment cycles according to multiple measurements.[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.

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

Date of preparation: June 2025 GL-RZ-2500033

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.
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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.

RYSTIGGO®▼ (rozanolixizumab) EU/EEA* Important Safety Information[1]

▼ *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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Indications: Rystiggo 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) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.[1]

The most commonly reported adverse reactions were headache (48.4%), diarrhoea (25.0%) and pyrexia (12.5%). The adverse reactions from clinical studies 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, and injection site reactions; Not known, aseptic meningitis (from spontaneous post-marketing reporting). 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. 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 and prescribing information. https://www.ema.europa.eu/

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

ZILBRYSQ®▼ (zilucoplan) EU/EEA* Important Safety Information[2]

▼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.

Indications: 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.[2]

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 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 prescribing information in relation to other side effects, full safety and prescribing

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information. Zilbrysq, INN-zilucoplan (europa.eu) Date of last revision: 28 April 2025. Date of preparation: April 2025.

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

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