UCB News

UCB presents expansive data set at 15th Myasthenia Gravis Foundation of America (MGFA) International Conference highlighting commitment to advancing gMG treatment outcomes and experiences

- UCB will contribute 21 presentations, including two final pooled analyses of the Phase 3 MycarinG study and the Open-Label Extension Studies focusing on the efficacy and safety of repeated rozanolixizumab treatment cycles in patients with generalized myasthenia gravis, demonstrating consistent improvements across MG-specific outcomes up to 13 cycles and that rozanolixizumab was generally well tolerated.[1,2]
- A 120-week post hoc analysis of RAISE-XT, which examines early and sustained response over time with zilucoplan in the treatment of generalized myasthenia gravis.[3]
- Findings from the Phase 3, open-label, crossover (MG0020) study evaluating patient preferences, experiences and safety of self-administered of rozanolixizumab.[4]

Brussels (Belgium), 13 May 2025, 07:00 (CET) UCB (Euronext Brussels: UCB), a global biopharmaceutical company, today announced that it will be presenting multiple important data sets from across its targeted treatment portfolio in generalized myasthenia gravis (gMG) at the Myasthenia Gravis Foundation of America (MGFA) International Conference taking place May 13-15, 2025, at The Hague, The Netherlands.

Across a total of 21 abstracts, data will be featured from studies of UCB's medicines for the treatment of gMG in adult patients; RYSTIGGO®▼(rozanolixizumab) and ZILBRYSQ®▼ (zilucoplan), along with findings from real-world studies of clinical outcomes and patient experience in gMG.

"Our presentations at the 15th MGFA Conference underscore our dedication to advancing understanding and treatment of generalized myasthenia gravis. We are excited to share new data sets on the long-term efficacy and safety of rozanolixizumab, and the early and sustained response over time with zilucoplan," said Donatello Crocetta, Chief Medical Officer, UCB. "In line with our commitment to patient-centered care, we are proud that UCB has funded and is the first subscriber to the Vitaccess Real MG Registry".

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

- Two final pooled analyses of the Phase 3 MycarinG study, and the Open-Label Extension Studies, focusing on the efficacy and safety of rozanolixizumab over multiple symptom-driven cycles in patients with generalized MG.[1,2]
- A 120-week post hoc analysis of RAISE-XT, which examines early and sustained response over time with zilucoplan in the treatment of generalized myasthenia gravis.[3]
- Findings from the Phase 3, open-label, crossover (MG0020) study evaluating patient preferences, experiences and safety of self-administered rozanolixizumab.[4]
- Presentation of the new Vitaccess Real MG (VRMG) Registry international patient registry design for myasthenia gravis.[5]
- An evaluation of the effect of Zilucoplan on Myasthenia Gravis Activities of Daily Living (MG-ADL) scale and Quantitative Myasthenia Gravis (QMG) ocular subdomain scores in patients with generalized myasthenia gravis in RAISE and RAISE-XT.[6]

Inspired by patients.
Driven by science.

- A poster for a matching-adjusted indirect comparisons (MAIC) study of zilucoplan versus eculizumab and ravulizumab in the treatment of generalized myasthenia gravis (gMG).* The findings are expected to provide insights into the potential for zilucoplan to offer improved outcomes.[7]

* The findings based on indirect comparisons should be interpreted with caution

UCB presentations at MGFA 2025

Lead author	Title	Presentation details
Carlo Antozzi, et al	Patient Preferences and Experience With Self-Administration of Rozanolixizumab in gMG: The MG0020 Study	Poster
Ali Habib, et al	Long-Term Efficacy and Safety of Rozanolixizumab Treatment Cycles in Patients With gMG: Final Pooled Analysis of MycarinG and Open-Label Extension Studies	Poster
Tuan Vu, et al	Responder and MSE Rates with Rozanolixizumab in gMG: Final Pooled Analysis of MycarinG and Open-Label Extension Studies	Poster
Sabrina Sacconi, et al	Effect of Rozanolixizumab on Bulbar and Respiratory Symptoms in Patients with gMG: Post Hoc Item-Level Analysis of MycarinG	Poster
Robert Pascuzzi, et al	Effect of Rozanolixizumab on Ocular Symptoms in Patients With gMG: A Post Hoc Item-Level Analysis of Myasthenia Gravis-Specific Outcomes in MycarinG	Poster
Robert Pascuzzi, et al	Effect of Rozanolixizumab on Myasthenia Gravis-Specific Outcome Subdomain Scores: Post Hoc Analyses from the Phase 3 MycarinG Study	Poster
Ali Habib, et al	Rozanolixizumab Treatment Patterns in Patients With gMG: Post Hoc Analysis	Poster
Julian Grosskreutz, et al	The Safety and Efficacy of Chronic Weekly Rozanolixizumab Treatment in Patients with gMG (MG0004)	Poster
Isabel Leite, et al	Improvement of Ocular Subdomain Scores With Zilucoplan in Patients With gMG in RAISE and RAISE-XT Studies	Poster
Channa Hewamadduma, et al	Early and Sustained Response Over Time with Zilucoplan in gMG: 120-Week Post Hoc Analysis of RAISE-XT	Poster
Isabel Leite, et al	Long-Term Use of Prophylactic Antibiotics in Addition to Meningococcal Vaccines During Treatment With Zilucoplan: Single Site Experience From Phase 3 Studies	Poster
April Betts, et al	Zilucoplan versus eculizumab and ravulizumab for treating generalised myasthenia gravis: matching-adjusted indirect comparisons	Late-Breaker Poster
Channa Hewamadduma, et al	Corticosteroid Dose Tapering During Treatment With Zilucoplan in Patients With gMG: 120-Week Follow-Up of RAISE-XT	Poster
Jens Schmidt, et al	Concomitant Intravenous Immunoglobulin or Plasma Exchange Has No Effect on Complement Inhibition by Zilucoplan	Poster
Miriam Freimer, et al	Switching to Subcutaneous Zilucoplan From IV Complement Component 5 Inhibitors in gMG: Patient Preference and Satisfaction From a Phase 3b Study	Poster

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Tuan Vu, et al	Non-Steroidal Immunosuppressant Therapy Changes During Treatment with Zilucoplan in Patients with gMG: 120-Week Follow-Up of RAISE-XT	Poster
David Reyes-Leiva, et al	Myasthenia Gravis Control: Evolution over Eight Years of Follow-up and Patient Characteristics	Poster
Andreas Meisel, et al	Adaptation of the Myasthenia Gravis Symptom Patient-Reported Outcome scales for use in clinical practice and observational studies	Poster
Kenza Seddik, et al	Exploratory Qualitative Study of Women's Lived Experiences With Myasthenia Gravis	Poster
Fatemeh Amini, et al	A Novel International Patient Registry in Myasthenia Gravis Linking Clinical and Patient-Reported Outcomes Data: The Vitaccess Real MG (VRMG) Registry	Poster
James Howard, et al	Developing Needs-Driven Medical Education for Healthcare Professionals in Myasthenia Gravis	Poster

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Important Safety Information about RYSTIGGO®▼ (rozanolixizumab) in the EU[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.

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,

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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.

Important Safety Information about ZILBRYSQ®▼ (zilucoplan) in the EU[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.

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%)). Zilucoplan is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients. The most common reactions were injection site bruising, pain, nodule, pruritus and haematoma. All cases were mild or moderate in severity, and less than 3% of reactions led to treatment discontinuation. The most common infections were nasopharyngitis, upper respiratory tract infection and sinusitis. More than 95% of the cases were mild or moderate in severity and did not lead to treatment discontinuation. In pooled placebo-controlled studies, upper respiratory tract infections were reported in 13.0% of patients treated with zilucoplan and in 7.8% of patients treated with placebo. Cases of lipase increase (5.2%) and/or amylase increase (6.1%) were observed. These elevations were transient and rarely led to treatment discontinuation. The majority occurred within 2 months of starting zilucoplan and normalized within 2 months. Elevations of blood eosinophils were observed. These were transient and not leading to treatment discontinuation. The majority occurred within 2 months of starting

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zilucoplan and normalized within 1 month. Cases of morphoea were observed after long-term treatment during the open-label extension study. The majority of the cases had a time to onset longer than one year after start of treatment, were mild or moderate in severity and did not lead to treatment discontinuation. 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. There are no data from the use of zilucoplan in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Treatment of pregnant women with Zilbrysq should only be considered if the clinical benefit outweighs the risks.

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 9 000 people in approximately 40 countries, the company generated revenue of € 6.1 billion in 2024. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

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[1] Vu, et al. Responder and MSE Rates with Rozanolixizumab in gMG: Final Pooled Analysis of MycarinG and Open-Label Extension Studies.
[2] Habib, et al. Long-Term Efficacy and Safety of Rozanolixizumab Treatment Cycles in Patients With gMG: Final Pooled Analysis of MycarinG and Open-Label Extension Studies.
[3] Hewamadduma, et al. Early and Sustained Response Over Time with Zilucoplan in gMG: 120-Week Post Hoc Analysis of RAISE-XT.
[4] Antozzi, et al. Patient Preferences and Experience With Self-Administration of Rozanolixizumab in gMG: The MG0020 Study.
[5] Amini, et al. A Novel International Patient Registry in Myasthenia Gravis Linking Clinical and Patient-Reported Outcomes Data: The Vitaccess Real MG (VRMG) Registry.
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[7] Betts, et al. Zilucoplan versus eculizumab and ravulizumab for treating generalised myasthenia gravis: matching-adjusted indirect comparisons.
[8] RYSTIGGO® EU SmPC. https://www.ema.europa.eu/en/documents/product-information/rystiggo-epar-product-information_en.pdf. Accessed April 2025.
[9] ZILBRYSQ® EU SmPC. https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf. Accessed April 2025.

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