UCB News

UCB spotlights new analyses and patient insights supporting its recently launched gMG portfolio at the 10th Congress of the European Academy of Neurology (EAN)

- **New data and real-world evidence in generalized myasthenia gravis (gMG) shared across 7 abstracts including 5 e-presentations**
- **Showcasing new data analyses for UCB's gMG treatments, including post hoc and open-label extension study results highlighting the long-term safety, efficacy, and patient-reported outcomes for recently approved RYSTIGGO®▼ (rozanolixizumab) and ZILBRYSQ®▼ (zilucoplan)**
- **Presentations follow recent U.S., EU, and Japanese approvals of zilucoplan and rozanolixizumab for the treatment of gMG in adult patients**

Brussels (Belgium), 28 June 2024: 07:00 (CET) UCB (Euronext Brussels: UCB), a global biopharmaceutical company, today unveiled details from their latest research findings - supporting recently launched treatments in its generalized myasthenia gravis (gMG) portfolio - to be presented at the 10th Congress of the European Academy of Neurology (EAN) June 29 - July 2, 2024, in Helsinki, Finland.

A total of 7 abstracts, including 5 e-presentations, will feature data from studies of UCB's recently approved medicines for the treatment of gMG, RYSTIGGO®▼ and ZILBRYSQ®▼, along with findings from real-world studies of clinical outcomes and patient experience in gMG.

Key UCB scientific and real-world data to be presented at EAN include:

- Post hoc and open-label extension analyses from the pivotal Phase 3 MycarinG study for rozanolixizumab in adult patients with gMG, including long-term safety and patient-reported outcomes, including physical fatigue.
- RAISE XT trials for zilucoplan, including e-presentations on long-term safety and efficacy of zilucoplan in gMG over 96 weeks, and a post hoc analysis of long term response rates over 60 weeks.
- Posters bringing new insights into different aspects of MG, demonstrating UCB's ongoing commitment to understanding patients' lived experience of the disease.

"The new insights being presented at this year's EAN congress underline our commitment to understanding the symptom burden and impact of myasthenia gravis from the patient's perspective. The new analyses from the Phase 3 and Open-Label Extension MycarinG and RAISE XT studies respectively provide clinicians with additional evidence to support their understanding of these new treatments and the role they could play in long-term disease management and gMG patients' outcomes." commented Donatello Crocetta, Head of Global Rare Disease & Rare Medical, UCB. *"These data further underscore UCB's approach to responding to unmet needs in gMG with treatments tailored to patients' individual needs and preferences."*

▼*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.*

Inspired by patients.
Driven by science.

UCB News

UCB presentations during EAN 2024

Lead author	Abstract title	Presentation Details (Timings ET)
C Hewamadduma	Response over time with zilucoplan in generalised myasthenia gravis: Post hoc analysis of RAISE-XT 60-week follow up	ePresentation Sunday, 30 Jun, 14:15 - 14:20 EEST
MI Leite	Long-term zilucoplan in generalised myasthenia gravis: 96-week follow-up interim analysis of RAISE-XT	ePresentation Sunday, 30 Jun, 14:35 - 14:40 EEST
J Vissing	Long-term safety outcomes of rozanolixizumab treatment in patients with generalised myasthenia gravis: A pooled analysis	ePresentation Saturday, 29 Jun, 14:15 - 14:20 EEST
S Sacconi	Rozanolixizumab in Generalised Myasthenia Gravis: Patient-Reported Outcomes in the Randomised, Phase 3, MycarinG study	ePresentation Saturday, 29 Jun, 14:30 - 14:35 EEST
C Antozzi	Minimal symptom expression in generalised myasthenia gravis: A post hoc analysis of MycarinG and open-label studies	ePresentation Saturday, 29 Jun, 14:05 - 14:10 EEST
PE Villy	Characterisation of patients with myasthenia gravis in France: a cluster analysis of patients from the online SPOON study	ePoster Tuesday, 2 Jul, 12:58 - 13:01 EEST
D Reyes-Leiva	Myasthenia Gravis Control: Evolution over Eight Years of Follow-up and Patient Characteristics	ePoster (Virtual)

"EAN coincides with the conclusion of MG Awareness Month in June, which highlights the challenges faced by those diagnosed with myasthenia gravis and their caregivers; it underlines the urgency to address the high disease and treatment burden, as well as the psychological and socioeconomic consequences of gMG that impact daily living and employment," said Manuela Maronati, Head of Europe, Rare Disease, UCB. *"As well as increasing our understanding of gMG in terms of treatment targets from a patient perspective, we are excited to be sharing our data and contributing to debate and discussion about progressing treatment options for people living with gMG."*

For delegates attending EAN 2024, UCB will be hosting an exhibition throughout the meeting, describing its heritage in neurology and its portfolio of medicines for the treatment of Epilepsy and gMG. Additionally, for registered healthcare professionals, UCB has arranged for a program of sponsored scientific and therapeutic updates. Visit us on our booth (exhibition hall E19) for more information.

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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.*

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) 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.

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

Date of last revision: 20 June 2024

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.

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 information.https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf.

Date of last revision: 25 May 2024.

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

Important Safety Information about RYSTIGGO® (rozanolixizumab-noli) in the US[3]

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.

Please refer to the full Prescribing Information (https://www.ucb-usa.com/RYSTIGGO-prescribing-information.pdf) provided by the UCB representative, and visit www. RYSTIGGO.com

Important Safety Information about ZILBRYSQ® (zilucoplan) in the US[4]

INDICATION

ZILBRYSQ (zilucoplan) is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update meningococcal vaccination (for serogroups A, C, W, and Y, and serogroup B) at least 2 weeks prior to administering the first dose of ZILBRYSQ, unless the risk of delaying therapy outweighs the risk of developing a meningococcal infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.**
- **Persons receiving ZILBRYSQ are at increased risk for invasive disease caused by *N. meningitidis*, even if they develop antibodies following vaccination. Monitor patients for signs of 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 in patients with unresolved *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. The use of ZILBRYSQ increases a patient's susceptibility to serious and life-threatening meningococcal infections (septicemia and/or meningitis) caused by any serogroup, including non-groupable strains.

Complete or update meningococcal vaccination (for both serogroups A, C, W, and Y [MenACWY] and serogroup B [MenB]) at least 2 weeks prior to administering the first dose of ZILBRYSQ, according to current ACIP recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.

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

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Withhold administration of ZILBRYSQ in patients who are undergoing treatment for meningococcal infection until the infection is resolved.

ZILBRYSQ REMS
Due to the risk of 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 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
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* and *Haemophilus influenzae type b* (Hib) infections according to ACIP guidelines. Persons receiving ZILBRYSQ are at increased risk for infections due to these bacteria, even after 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 see the full Prescribing Information (https://www.ucb-usa.com/zilbrysq-prescribing-information.pdf) **for additional Important Safety Information.**

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 €5.3 billion in 2023. 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: 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.

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1. RYSTIGGO®▼EU SmPC. https://www.ema.europa.eu/en/documents/product-information/rystiggo-epar-product-information_en.pdf. (Accessed June 2024).
2. ZILBRYSQ®▼EU SmPC. https://www.ema.europa.eu/en/documents/product-information/zilbrysq-epar-product-information_en.pdf. (Accessed June 2024).
3. RYSTIGGO® US PI. https://www.ucb-usa.com/RYSTIGGO-prescribing-information.pdf (Accessed: June 2024).
4. ZILBRYSQ® US PI. https://www.ucb-usa.com/zilbrysq-prescribing-information.pdf (Accessed: June 2024).