UCB News

UCB announces U.S. FDA approval of ZILBRYSQ® (zilucoplan) for the treatment of adults with generalized myasthenia gravis

- FDA approval of ZILBRYSQ® (zilucoplan) has been granted for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody-positive[1]
- Zilucoplan is the first once-daily subcutaneous, targeted C5 complement inhibitor for gMG. It is the only once-daily gMG-target therapy for self-administration
- U.S. FDA approval of zilucoplan is built on the pivotal Phase 3 RAISE study in gMG[2], which demonstrated that treatment with zilucoplan resulted in statistically significant improvements in MG-specific efficacy outcomes compared to placebo
- With the FDA approval of zilucoplan, and with RYSTIGGO® (rozanolixizumab-noli) already FDA approved and launched in the U.S[3], UCB is the first organization to offer the U.S. gMG community the opportunity to benefit from a choice of two new targeted therapies from a single company
- UCB's portfolio of two different medicines for gMG, each with a distinct mechanism of action, offers physicians new and additional choices, embodying our commitment to addressing the gMG community's unmet needs

Brussels (Belgium) 17 October 2023 – UCB (Euronext Brussels: UCB), a global biopharmaceutical company, today announced that ZILBRYSQ® (zilucoplan) has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody-positive.[1]

Zilucoplan is the first once-daily subcutaneous (SC), targeted peptide inhibitor of complement component 5 (C5 inhibitor)[2]. It is the only once-daily gMG target therapy for self-administration by adult patients with anti-AChR antibody-positive gMG.

As a complement C5 inhibitor, zilucoplan inhibits complement-mediated damage to the neuromuscular junction through its targeted mechanism of action.[2] Benefits of self-administered treatment compared with intravenously administered treatments can include reduced traveling time to and from hospitals, decreased interference with work obligations, and increased independence. Unlike monoclonal antibody C5 inhibitors, as a peptide, zilucoplan can be used concomitantly with intravenous immunoglobulin and plasma exchange, without the need for supplemental dosing.[2]

The FDA approval of zilucoplan[1] is supported by safety and efficacy data from the RAISE study (NCT04115293), published in *The Lancet Neurology* in May 2023.[2] The RAISE study was a multi-center, phase 3, randomized, double-blind, placebo-controlled study to assess 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 study demonstrated that zilucoplan delivered rapid, consistent, and statistically significant benefits in different patient-and-clinician reported outcomes at week 12 in a broad population of adult patients with mild-to-severe anti-AChR-antibody positive gMG. The most common adverse reactions (≥10%) in patients with gMG were injection site reactions, upper respiratory tract infection, and diarrhea.

"For people with gMG, the unpredictable nature of the severity and frequency of symptoms can be debilitating and can have a substantial impact on many aspects of their day-to-day lives. In addition to muscle weakness, people living with gMG experience fatigue, affecting their overall quality of life," said James F. Howard, MD, Distinguished Professor of Neuromuscular Disease, Professor of Neurology, Medicine and Allied Health, The University of North Carolina at Chapel Hill School of Medicine and lead investigator in the RAISE trial. *"Zilucoplan demonstrated rapid improvements in gMG symptoms at Week 12, with differences seen as early as one week, and provides a new treatment option for a broad population of AChR antibody-positive gMG patients. Zilucoplan is designed for continued daily use."*

gMG is a rare, chronic, heterogeneous, unpredictable autoimmune disease characterized by dysfunction and damage at the neuromuscular junction (NMJ).[4,5,6] Several factors are understood to be drivers of gMG disease pathology, including the complement cascade, immune cells and pathogenic Immunoglobulin G (IgG) autoantibodies. [7]

In anti-AChR antibody-positive gMG, pathogenic AChR autoantibodies (IgG1 and IgG3) initiate the classical complement pathway, leading to the cleavage of C5 and the MAC (membrane attack complex) formation, damage to the NMJ, loss of AChRs and subsequent impaired synaptic transmission.[6,8,9] Preventing MAC formation reduces damage to the post-synaptic membrane, reduces disruption of ionic channel conductance and helps to preserve neuromuscular transmission.[8] MG has a global prevalence of 100–350 cases per every 1 million people.[5]

"This is an important development for the community because, with more FDA-approved treatments for generalized myasthenia gravis, physicians have additional tools to treat this disease in individualized ways that are the right fit for each individual patient," said Samantha Masterson, President and Chief Executive Officer of the Myasthenia Gravis Foundation of America*. "We are so grateful to UCB for being part of the myasthenia gravis community and their continued commitment to finding solutions for people living with this chronic, autoimmune, neuromuscular disease."*

With the approval of zilucoplan, alongside the company's neonatal Fc receptor (FcRn) blocker RYSTIGGO® (rozanolixizumab-noli), which was approved earlier this year by the FDA under Priority Review designation 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, UCB's portfolio provides healthcare professionals the option of addressing either complement activation or pathogenic auto-antibodies for appropriate patients.[3,10]

"With the FDA approval for zilucoplan, we are very proud and excited to expand our support to the gMG community. Following the FDA approval and strong momentum with our FcRn inhibitor rozanolixizumab-noli and with our tailored patient support services and commitment to widespread access, I am confident that UCB is the only company with a portfolio of two targeted therapies with different mechanisms of action and the experience to deliver truly individualized transformational patient value to people living with this often debilitating rare disease" said Jean-Christophe Tellier, CEO, UCB. "*We would like to extend our thanks to the patients, care partners, and investigators who participated in the RAISE study, and to our employees and collaborators, whose dedication and commitment to the gMG community made this important milestone possible*."

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. The MG-ADL is an eight-item patient-reported outcome measure assessing MG symptoms and functional activities related to activities of daily living.[11] These include activities

GL-ZL-2300006 Date of preparation: October 2023

such as breathing, talking, swallowing, and being able to rise from a chair.[12] Each of the items is scored, from 0 (normal) to 3 (most severe), providing a total MG-ADL score ranging from 0 to 24, where higher scores indicate greater severity of symptoms.[2]

The efficacy of zilucoplan was also measured, as a secondary endpoint, using the Quantitative Myasthenia Gravis (QMG) total score which is a 13-item categorical grading system that assesses muscle weakness. Each item is assessed on a 4-point scale where a score of 0 represents no weakness and a score of 3 represents severe weakness. A total possible score ranges from 0 to 39, where higher scores indicate more severe impairment.[11]

At week 12, treatment with zilucoplan demonstrated a statistically significant improvement from baseline compared to placebo for MG-ADL total score and QMG total score. Other secondary endpoints included the proportion of patients with improvements of at least 3 and 5 points in the MG-ADL total score and QMG total score, respectively, at week 12 without rescue therapy.[2]

"Until now, people living with gMG have only had access to C5 therapy intravenously, which can be inconvenient and time consuming. Now, with the option of zilucoplan, a self-administered once-daily, subcutaneous targeted complement C5 inhibitor, we hope a broad population of mild-to-severe adult patients with AChR-antibody-positive gMG will be able to have greater independence" said Iris Loew-Friedrich, Executive Vice-President and Chief Medical Officer at UCB. *"Alongside our FcRn blocker rozanolixizumab-noli, which was approved and launched in the U.S. earlier this summer, our unique portfolio will support patients and healthcare professionals to tailor choice of treatment according to their individual needs."*

About zilucoplan

Zilucoplan is a once-daily, SC, self-administered peptide inhibitor of complement component 5 (C5 inhibitor). As the only once-daily gMG target therapy for self-administration by adult patients with anti-AChR antibody-positive gMG, zilucoplan inhibits complement-mediated damage to the neuromuscular junction through its targeted mechanism of action.[2]

In September 2023, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending granting marketing authorization for zilucoplan in the European Union (EU) 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.[13] A final decision on approval in the EU is expected before the end of the year, in line with the EMA's standard review timeline.

Also in September 2023, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved zilucoplan for the treatment of gMG in adult patients who inadequately respond to steroids or other immunosuppressants.[14]

Zilucoplan is currently under review by the Australian Therapeutic Goods Administration (TGA) and Health Canada for the treatment of adults with gMG. Responses from regulatory agencies to these submissions are expected between H2 2023 and H2 2024.

Orphan designation was granted by the FDA in 2019 to zilucoplan for the treatment of myasthenia gravis.[14]

About generalized Myasthenia Gravis (gMG)

GL-ZL-2300006 Date of preparation: October 2023

gMG is a rare autoimmune disease with a global prevalence of 100–350 cases per every 1 million people.[5] 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.[4,16]

In MG, pathogenic autoantibodies can impair synaptic transmission at the neuromuscular junction (NMJ) by targeting specific proteins on the post-synaptic membrane.[17] This disrupts the ability of the nerves to stimulate the muscle and results in a weaker contraction. gMG can occur in any race, gender or age.[4,16]

About the RAISE study[2]

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 from baseline to Week 12. Other secondary efficacy outcomes, time to first receipt of rescue therapy over 12 weeks, the proportion of patients with minimal symptom expression (MSE) (defined as MG-ADL of 0 or 1 without rescue therapy), the proportion of patients with a ≥3-point reduction in MG-ADL without rescue therapy and the proportion of patients with a ≥5-point reduction in QMG without rescue therapy, all measured at Week 12.

Safety was assessed by the incidence of treatment-emergent adverse events (TEAEs).

Patients who completed the RAISE trial had the possibility to enter the open-label extension study, RAISE-XT (NCT04225871).[2]

For more information about the trial, visit https://clinicaltrials.gov/ct2/show/NCT04115293.

About rozanolixizumab-noli

In addition to zilucoplan, UCB's gMG portfolio includes the FDA-approved medicine RYSTIGGO® (rozanolixizumab-noli), a subcutaneously infused monoclonal antibody targeting the neonatal Fc receptor (FcRn).[9]

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).[3,10]

In September 2023, rozanolixizumab was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of gMG in adult patients who inadequately respond to steroids or other immunosuppressants.[14]

Rozanolixizumab is currently under review by the European Medicines Agency (EMA), the Australian Therapeutic Goods Administration (TGA) and Health Canada for the treatment of adults with gMG. Responses from regulatory agencies to these submissions are expected during H2 2023 and H1 2024.

Important Safety Information for ZILBRYSQ®

GL-ZL-2300006 Date of preparation: October 2023

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

What is the most important information I should know about ZILBRYSQ?

ZILBRYSQ is a medicine that affects part of your immune system. ZILBRYSQ may lower the ability of your immune system to fight certain infections.

- ZILBRYSQ increases your chance of getting serious and life-threatening meningococcal infections. Meningococcal infections may become life-threatening or fatal if not recognized and treated early.
  - You must complete or update two types of meningococcal vaccines (for both serogroup B infections and serogroup A, C, W, and Y infections) at least 2 weeks before your first dose of ZILBRYSQ if you have not already had these vaccines.
  - If your healthcare provider decided that urgent treatment with ZILBRYSQ is needed, you should receive meningococcal vaccination(s) as soon as possible.
  - If you have not completed or updated vaccinations for meningococcal infections at least 2 weeks before your first ZILBRYSQ dose and ZILBRYSQ therapy must be started right away, you must also receive antibiotics.
  - If you had a meningococcal vaccine in the past, you might need additional vaccination before starting ZILBRYSQ. Your healthcare provider will decide if you need additional meningococcal vaccination.
  - Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:**

    - headache with nausea or vomiting
    - headache and fever
    - headache with a stiff neck or stiff back
    - fever
    - fever and a rash
    - confusion
    - muscle aches with flu-like symptoms
    - eyes sensitive to light

Your healthcare provider will give you a Patient Safety Card about the risk of meningococcal infection. Carry it with you at all times during treatment and for 2 months after your last ZILBRYSQ dose. Your risk of meningococcal infection may continue for several weeks after your last dose of ZILBRYSQ. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

ZILBRYSQ is only available through a program called the ZILBRYSQ REMS. Before you can receive ZILBRYSQ, your healthcare provider must:

- enroll in the ZILBRYSQ REMS.
- counsel you about the risk of meningococcal infection.
- give you the Patient Guide, including information about the signs and symptoms of meningococcal infection.
- give you a **Patient Safety Card** about your risk of meningococcal infection, as discussed above.
- make sure that you are vaccinated with two types of meningococcal vaccines and, if needed, get revaccinated with the meningococcal vaccines. Ask your healthcare provider if you are not sure if you need to be revaccinated.

GL-ZL-2300006 Date of preparation: October 2023

ZILBRYSQ may also increase the risk of other types of serious infections.

- ZILBRYSQ may increase your chance of getting *Streptococcus pneumoniae* and *Haemophilus influenzae* type b. Your healthcare provider will tell you if you should receive the *Streptococcus pneumoniae* and *Haemophilus influenzae* type b vaccinations.
- Certain people may have an increased risk of gonorrhea infection. Talk to your healthcare provider about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and about regular testing.

Call your healthcare provider right away if you have new signs or symptoms of infection.

Who should not use ZILBRYSQ?

Do not use ZILBRYSQ if you have a *Neisseria meningitidis* infection.

Before you use ZILBRYSQ, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever.
- are pregnant or plan to become pregnant. It is not known if ZILBRYSQ will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZILRYSQ passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use ZILBRYSQ.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of ZILBRYSQ?

ZILBRYSQ may cause serious side effects, including:

- See **"What is the most important information I should know about ZILBRYSQ?"**
- **Inflammation of the pancreas (pancreatitis) and other pancreatic problems.** Pancreatitis and pancreatic cysts have happened in people who use ZILBRYSQ. Your healthcare provider will do blood tests to check your pancreas before you start treatment with ZILBRYSQ.
  - **Call your healthcare provider right away** if you have pain in your stomach area (abdomen) that will not go away. Your healthcare provider will tell you if you should stop using ZILBRYSQ. The pain may be severe or felt going from your abdomen to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

The most common side effects of ZILBRYSQ include:

- injection site reactions.
- upper respiratory tract infections.
- diarrhea.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of ZILBRYSQ. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at www.fda.gov/medwatch or 1-800-FDA-1088. You may also report side effects to UCB, Inc. by calling 1-844-599-CARE [2273].

GL-ZL-2300006 Date of preparation: October 2023

See the detailed Instructions for Use that comes with ZILBRYSQ for information on how to prepare and inject a dose of ZILBRYSQ, and how to properly throw away (dispose of) used ZILBRYSQ prefilled syringes.

INDICATION
What is ZILBRYSQ?

- ZILBRYSQ is a prescription medicine used to treat adults with a disease called generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
- It is not known if ZILBRYSQ is safe and effective in children.

Please see the full Prescribing Information and Medication Guide for ZILBRYSQ, including Boxed Warning regarding serious meningococcal infections. Please see the Instructions for Use for the ZILBRYSQ Single-Dose Prefilled Syringe. Talk to your healthcare provider about your condition or your treatment. For more information, go to www.ZILBRYSQ.com or call 1-844-599-2273.

Important Safety Information for RYSTIGGO®

IMPORTANT SAFETY INFORMATION AND INDICATION

WHAT IS RYSTIGGO?
RYSTIGGO is a prescription medicine used to treat adults with a disease called generalized myasthenia gravis (gMG) who are acetylcholine receptor (anti-AChR) antibody positive or muscle-specific tyrosine kinase (anti-MuSK) antibody positive.[18]

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT RYSTIGGO (rozanolixizumab-noli)?
RYSTIGGO may cause serious side effects, including:

- **Infection:** RYSTIGGO may increase the risk of infection. In clinical studies, the most common infections were upper respiratory tract infections, COVID-19, urinary tract infections, and herpes simplex infections. Your healthcare provider should check you for infections before starting and during treatment with RYSTIGGO. Tell your healthcare provider if you have any history of infections. Tell your healthcare provider right away if you have signs or symptoms of an infection during treatment with RYSTIGGO. Some of the signs and symptoms may include fever, chills, frequent and/or painful urination, cough, runny nose, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.[18]
- **Aseptic Meningitis:** RYSTIGGO could cause aseptic meningitis. Tell your healthcare provider right away if you develop any signs or symptoms of meningitis during treatment with RYSTIGGO such as severe headache, neck stiffness, drowsiness, fever, sensitivity to light, painful eye movements, nausea, and vomiting.[18]
- **Hypersensitivity Reactions:** RYSTIGGO can cause swelling and rash. Your healthcare provider should monitor you during and after treatment and discontinue RYSTIGGO if needed. Tell your healthcare provider immediately about any undesirable reactions you experience after administration.[17]

Before taking RYSTIGGO, tell your healthcare provider about all of your medical conditions, including if you:

GL-ZL-2300006 Date of preparation: October 2023

- Have a history of infection or think you have an active infection.
- Have received or are scheduled to receive a vaccine (immunization). The use of vaccines during RYSTIGGO treatment has not been studied, and the safety with live or live-attenuated vaccines is unknown. Administration of live or live-attenuated vaccines is not recommended during treatment with RYSTIGGO. Completion of age-appropriate vaccines according to vaccination guidelines before starting a new treatment cycle with RYSTIGGO is recommended.
- Are pregnant or plan to become pregnant or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF RYSTIGGO?
RYSTIGGO may cause serious side effects, including[18]:

- See **"What is the most important information I should know about RYSTIGGO?"**

The most common side effects of RYSTIGGO include[18]:

- headache
- infections
- diarrhea
- fever
- hypersensitivity reactions
- nausea

These are not all the possible side effects of RYSTIGGO. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effect that bothers you or that does not go away. Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to UCB, Inc. by calling 1-844-599-CARE [2273].

Please see the full Prescribing Information and talk to your healthcare provider about your condition or your treatment.

For further information, contact UCB:

Global Rare Disease Communications
Jim Baxter
T +32.2.473.78.85.01
jim.baxter@ucb.com

U.S. Rare Disease Communications
Daphne Teo
Daphne.teo@ucb.com
T +1-770-880-7655

Corporate Communications, Media Relations
Laurent Schots
T +32.2.559.92.64
Laurent.schots@ucb.com

GL-ZL-2300006 Date of preparation: October 2023

UCB News

Investor Relations
Antje Witte
T +32.2.559.94.14
antje.witte@ucb.com

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 8,600 people in approximately 40 countries, the company generated revenue of €5.5 billion in 2022. 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 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

GL-ZL-2300006 Date of preparation: October 2023

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, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

UCB is providing this information, including forward-looking statements, only as of the date of this press release and it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated otherwise. UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. UCB expressly disclaims any duty to update any information contained in this press release, 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.

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.

References:

1. ZILBRYSQ® U.S. Prescribing Information.
2. Howard JF Jr, et al. Safety and efficacy of zilucoplan in patients with generalised myasthenia gravis (RAISE): a randomised, double-blind, placebo-controlled, phase 3 study. Lancet Neurol. 2023;22(5):395-406.
3. US Food and Drug Administration. Novel Drug approvals for 2023. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023. Accessed October 2023.
4. National Institute of Neurological Disorders and Stroke. 2022. Myasthenia Gravis Fact Sheet. https://www.ninds.nih.gov/myasthenia-gravis-fact-sheet. Accessed October 2023.
5. Punga AR, et al. Epidemiology, diagnostics, and biomarkers of autoimmune neuromuscular junction disorders. Lancet Neurol. 2022;21(2):176-88.
6. Howard JF Jr. Myasthenia gravis: The role of complement at the neuromuscular junction. Ann N Y Acad Sci. 2018;1412(1):113–128.
7. Phillips WD, Vincent A. Pathogenesis of myasthenia gravis: Update on disease types, models, and mechanisms. F1000Res. 2016;5:F1000 Faculty Rev-1513.
8. Mantegazza R, et al. Complement inhibition for the treatment of myasthenia gravis. Immunotargets Ther. 2020;9:317–331.
9. Howard JF Jr, et al. Zilucoplan: An Investigational Complement C5 Inhibitor for the Treatment of Acetylcholine Receptor Autoantibody-Positive Generalized Myasthenia Gravis. Expert Opin Investig Drugs. 2021 May;30(5):483-493.
10. Bril V, et al. Safety and efficacy of rozanolixizumab in patients with generalised myasthenia gravis (MycarinG): a randomised, double-blind, placebo-controlled, adaptive phase 3 study. Lancet Neurol. 2023;22(5):383-94.
11. National Library of Medicine (NIH) Clinical Review Report: Eculizumab (Soliris): Alexion Pharma Canada Corporation: Indication: Adult patients with generalized myasthenia gravis [Internet]. Appendix 5. https://www.ncbi.nlm.nih.gov/books/NBK567509/#:~:text=Go%20to%3A-,Myasthenia%20Gravis%20Activities%20of%20Daily%20Living%20Scale%20(MG%2DADL),to%20activities%20of%20daily%20living. Accessed October 2023.
12. Wolfe GI, et al. Myasthenia gravis activities of daily living profile. Neurology. 192;52(7):1487-9

GL-ZL-2300006 Date of preparation: October 2023

13. CHMP Positive Opinion: Zilbrysq https://www.ema.europa.eu/en/medicines/human/summaries-opinion/zilbrysq Accessed October 2023.
14. UCB Data on file: Japan MHLW, 25 September 2023
15. US Food and Drug Administration. https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=699319. Accessed October 2023.
16. Myasthenia Gravis Foundation of America. MG Quick Facts. https://myasthenia.org/MG-Education/MG-Quick-Facts. Accessed October 2023.
17. Juel VC, Massey JM. Myasthenia gravis. Orphanet J Rare Dis. 2007;2:44.
18. RYSTIGGO® U.S. Prescribing Information.