UCB News

UCB presents latest data from generalized myasthenia gravis portfolio at 2023 American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting and Myasthenia Gravis Foundation of America (MGFA) Scientific Session

- 14 presentations – including 3 oral sessions – have been selected by AANEM and MGFA for inclusion within scientific programs
- Results presented across UCB's generalized myasthenia gravis (gMG) portfolio, including Open Label Extension data from the MycarinG and RAISE studies
- Presentations showcase additional data on RYSTIGGO® (rozanolixizumab-noli) and ZILBRYSQ® (zilucoplan), following recent regulatory approvals for the treatment of gMG in adult patients, alongside real-world MG data and its use in better understanding patient experiences
- UCB will also host a symposium, "New Horizons: Navigating a New Treatment Landscape for gMG" on November 1, 12:00 PM MT.

Brussels (Belgium), 1st November 2023: 07:00 (CET) UCB (Euronext Brussels: UCB), a global biopharmaceutical company, today announced that it will be presenting results from across its portfolio in generalized myasthenia gravis (gMG) at the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) annual meeting and the Myasthenia Gravis Association of America Scientific Session, taking place November 1-4, 2023.

Additional results from the MycarinG and RAISE studies,[1,2] and their open-label extension studies, will be presented, investigating UCB's rozanolixizumab-noli, a subcutaneously (SC)-injected monoclonal antibody targeting the neonatal Fc receptor (FcRn)[3,4] and zilucoplan, a self-administered, subcutaneously injected peptide inhibitor of complement component 5 (C5 inhibitor) in adults with gMG.[5] These two Phase 3 trials supported U.S., EU, and Japanese regulatory filings of both rozanolixizumab-noli and zilucoplan.

Zilucoplan was recently 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),[6] following FDA approval of rozanolixizumab-noli for treatment of gMG in adult patients who are anti-AChR antibody-positive or anti-muscle-specific tyrosine kinase (MuSK) antibody-positive earlier this year.[7] Zilucoplan and rozanolixizumab were also recently approved in Japan by the Japanese Ministry of Health, Labour and Welfare (MHLW)[8]. Both medicines are also under review by the European Medicines Agency (EMA) for the treatment of adults with gMG, with zilucoplan having recently received a positive CHMP opinion.

These data further inform UCB's innovative approach to evolving science into meaningful solutions that help improve outcomes and help address unmet needs of people living with gMG.

"*Additional results being presented at AANEM 2023 and the MGFA Scientific Sessions from the MycarinG and RAISE studies and their open-label extensions demonstrate UCB's commitment to finding treatment options that provide sustained efficacy for patients with gMG, and reinforce the depth and strength of our expanding rare*

disease pipeline and portfolio," said Donatello Crocetta, Head of Global Rare Disease & Rare Medical, UCB. *"Following on from our recent approvals for rozanolixizumab and zilucoplan in the U.S. and Japan for the treatment of adult patients with gMG, we're very excited to be contributing new treatment options to people living with this rare neuromuscular disease."*

As part of ongoing work to reveal better understanding of the patient and societal burden of gMG, UCB will also present posters on real-world data providing insights into the impact of social determinants of health on treatment of people with MG and the increase in risk of gMG exacerbation and healthcare resource utilization (HCRU) associated with higher MG-ADL scores.

Further demonstrating their commitment to finding solutions for unmet needs within the gMG community, UCB will also present study designs for Phase 2/3 studies to assess zilucoplan and rozanolixizumab-noli in pediatric patients with gMG.

In total, fourteen abstracts will be presented, including three as oral presentations.

"For people living with gMG, the burden of disease is great and it's important for us, as a company, to build the body of evidence around the complexities of this disease," said Kim Moran, Head of U.S. Rare Disease, UCB. *"We're committed to creating patient value by pursuing a portfolio of differentiated solutions that are aligned to the needs and objectives of the generalized myasthenia gravis community."*

UCB data included within MGFA Scientific Session:

Presenting author	**Abstract title**	**Presentation Details (Timings ET)**
Vera Bril	MG-ADL and QMG scores over time in patients with generalized Myasthenia Gravis: post-hoc analysis of MycarinG and open-label studies	Oral Presentation November 1, 2023 10:14 AM 10:21 AM
Sigrid Nilius	Zilucoplan in pediatric patients with AChR autoantibody-positive generalized Myasthenia Gravis: ZiMyG (MG0014) and ZiMyG+ (MG0015) clinical study designs	Oral Presentation November 1, 2023 10:21 AM – 10:28 AM
Miriam Freimer	Early responders with zilucoplan: an interim analysis of RAISE-XT in patients with generalized Myasthenia Gravis	Oral Presentation November 1, 2023 10:28 AM – 10:35 AM
Robert Pascuzzi	Efficacy of repeated cycles of rozanolixizumab treatment in subgroups of patients with generalized Myasthenia Gravis: a pooled analysis of a Phase 3 study and two Phase 3 open-label extension studies	Poster Presentation November 1, 2023
Ali Habib	Patient-reported outcomes during repeated cycles of rozanolixizumab treatment in patients with generalized Myasthenia Gravis in the Phase 3 MycarinG and open-label extension studies	Poster Presentation November 1, 2023
Ali Habib	Looking beyond the numbers: interpreting patient experience of rozanolixizumab in generalized Myasthenia Gravis from the MycarinG clinical trial	Poster Presentation November 1, 2023
Angela Ting (UCB)	Risk of Myasthenia Gravis exacerbation and level of healthcare resource utilization by MG-ADL score	Poster Presentation November 1, 2023

Judith Thompson (UCB)	Social determinants of health are associated with suboptimal treatment among individuals with Myasthenia Gravis	Poster Presentation November 1, 2023

UCB Data included in AANEM Scientific Program:

Ali Habib	Repeated cycles of rozanolixizumab treatment in patients with MuSK autoantibody-positive generalized Myasthenia Gravis	Poster Session I & III Poster number: 203
John Brandsema	Subcutaneous rozanolixizumab in pediatric patients with generalized Myasthenia Gravis: clinical study design	Poster Sesssion I & II Poster number: 204
Natasa Savic	Effect of zilucoplan on disease fluctuation in patients with generalized Myasthenia Gravis in the Phase 3 RAISE study	Poster Session I & II Poster number: 259
Tuan Vu	Response rates with zilucoplan among patients with generalized Myasthenia Gravis in an interim analysis of RAISE-XT, a Phase 3 open-label extension study	Poster Session I & II Poster number: 268
Tuan Vu	Long-term safety of repeated cycles of rozanolixizumab treatment in patients with generalized Myasthenia Gravis	Poster Session I & II Poster number: 269
Michael Weiss	Effect of zilucoplan on fatigue in generalized Myasthenia Gravis in the Phase 3 RAISE and RAISE-XT studies	Poster Session I & III Poster number: 285

In addition to contributing to the AANEM and MGFA scientific programme, UCB will be hosting a sponsored therapeutic update session entitled "New Horizons: Navigating a New Treatment Landscape for gMG" onsite at the congress venue on November 1 at 12:00 PM MT.

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 MG, 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 muscle and results in a weaker contraction. gMG can occur in any race, gender or age.[10,11]

About zilucoplan

Zilucoplan is a once-daily SC, self-administered peptide inhibitor of complement component 5 (C5 inhibitor). As the only once-daily generalized myasthenia gravis (gMG) target therapy for self-administration by adult patients with anti acetylcholine receptor (AChR) antibody-positive gMG, zilucoplan inhibits complement-mediated damage to the neuromuscular junction through its targeted mechanism of action.[13]

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.[6]

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 gMG in adult patients who are anti-AChR antibody-positive.[14] 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 (only for patients who inadequately respond to steroids or other immunosuppressants).[8]

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 during H2 2023 and H1 2024.

Orphan designation was granted by the FDA in 2019 to zilucoplan for the treatment of myasthenia gravis.[15]

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).[1,3]

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).[7]

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).[8]

Rozanolixizumab is currently under review by the European Medicines Agency (EMA), the Center of Drug Evaluation of the China National Medical Products Administration, the Australian Therapeutic Goods Administration (TGA), Health Canada and Switzerland (Swissmedic) 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®

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.

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 ZILBRYSQ 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].

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 the 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.

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.

- **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.
- **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.

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

- 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:

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

The most common side effects of RYSTIGGO include:

- 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

UCB News

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About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With 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 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.

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