UCB News

UCB receives positive CHMP opinion for new ZILBRYSQ® ▼ (zilucoplan) pre-filled pen in EU for adults living with generalized myasthenia gravis

- ZILBRYSQ® (zilucoplan) pre-filled pen offers the same complement component 5 (C5) inhibitor as the pre-filled syringe in a new device designed for simplicity, with a sustainable package design[1,2]
- First once-daily subcutaneous C5 inhibitor available as a pre-filled pen in Europe 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[1]
- Milestone reflects UCB's commitment to advancing science in generalized myasthenia gravis and in innovating treatment delivery and patient experience

Brussels (Belgium) 26 March 2026, 07:00 (CET) – UCB (Euronext Brussels: UCB), a global biopharmaceutical company, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending a variation to the terms of the marketing authorization for ZILBRYSQ® (zilucoplan), introducing a new additional device presentation via a pre-filled pen as an add-on to standard therapy for the treatment of adults living with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.[1,3]

Zilucoplan pre-filled pen is a self-administration device designed to automatically inject an accurate and defined dose of zilucoplan triggered by push-on-skin activation.[1,4] It is the first once-daily, subcutaneous C5 inhibitor for gMG in Europe commercially available as a pre-filled pen and provides an additional application option for adults with anti-AChR antibody-positive gMG.[1] Up to now, zilucoplan was approved in Europe to be self-administered subcutaneously by patients or caregivers using a pre-filled syringe injection.[1]

"The approval of the zilucoplan pre-filled pen reflects our commitment not only to advancing the science in generalized myasthenia gravis, but also to innovating how treatments are delivered and experienced," said Donatello Crocetta, MD, Chief Medical Officer at UCB. "By simplifying daily administration, this new device is designed to support confidence in self-management while delivering the same trusted therapy supported by the established clinical evidence of zilucoplan. Ultimately, it reinforces our focus on translating scientific innovation into meaningful improvements in patients' daily lives."

The pre-filled pen offers a portable solution that is designed to fit into patients' daily routines while delivering high self-injection satisfaction,[1,4] empowering patients to take control of their treatment journey at home.[5] As the needle in the pre-filled pen is not visible, it has the added benefit of potentially helping patients overcome needle-related concerns.[1,6]

This advancement significantly supports UCB's environmental goals as it features an optimized product and packaging design that achieves up to a 50% reduction in CO_2 emissions compared to other production methods.[2,7]

"When developing new delivery options, it is essential to generate robust clinical evidence that evaluates both the performance of the medicine and how it is used in real-world settings," said Dr. Mary Petrulis, Neurologist at The Ohio State University Wexner Medical Center. "For people living with generalized myasthenia gravis, the zilucoplan pre-filled pen may support confidence in daily treatment through a simplified administration approach.

GL-ZL-2600006 Date of preparation: March 2026

Its design allows patients to administer therapy as part of their routine, while preserving the established clinical profile of the therapy."

Supporting data

Data from two clinical studies* DV0012 and DV0013 demonstrated bioequivalence between zilucoplan pre-filled pen and pre-filled syringe and successful self-administration with the pre-filled pen.[4] UCB will present these data at this year's *American Academy of Neurology* (AAN) meeting, Chicago, Illinois, April 18-22, 2026. The DV0012 study (NCT06511076) established zilucoplan bioequivalence in healthy volunteers between the pre-filled pen and pre-filled syringe, thereby confirming that the pre-filled pen may be an effective alternative for zilucopan administration.[1,4] In a separate study in adults with gMG, results from the DV0013 study (NCT06471361) showed that self-administration with the pre-filled pen achieved complete dose delivery in 99.8% of administrations, and was generally well tolerated.[4] Additionally, at day 14 median (range) 'satisfaction with self-injection' score, measured as part of the Self-Injection Assessment Questionnaire, results showed a score of 8.9 (6-10).[4]

About zilucoplan

Zilucoplan is a once-daily SC, self-administered peptide inhibitor of complement component 5 (C5 inhibitor). As a C5 inhibitor, zilucoplan inhibits complement-mediated damage to the neuromuscular junction through its targeted dual mechanism of action.[1,5] Zilucoplan received European Commission approval in December 2023 as an add-on to standard therapy for the treatment of adults with anti-AChR antibody-positive gMG.[2] The approval was supported by safety and efficacy data evaluated in a 12-week multicenter, randomized, double-blind placebo-controlled study MG0010 (RAISE) and the open-label extension study MG0011 (RAISE XT). Zilucoplan met the primary endpoint in RAISE which was change from baseline to week 12 in MG-ADL total score versus placebo.[1]

About generalized Myasthenia Gravis (gMG)

gMG is a rare autoimmune disease with a global prevalence of 100–350 cases per every 1 million people.[8] 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.[9,10]

**DV0012 was a Phase 1, open-label, single-center, two-period crossover study in healthy adult volunteers randomized 1:1 to one of two treatment sequences: single injection with ZLP-AI (auto-injector) then ZLP-PFS (pre-filled syringe), or ZLP-PFS then ZLP-AI. Primary PK parameters estimated were area under the curve (AUC), AUC up to last quantifiable concentration (AUC_{0-t}) and maximum observed concentration (C_{max}). DV0013 was a Phase 3b, open-label, multicenter study, in patients with gMG either participating in RAISE-XT (NCT04225871) or receiving commercially administered zilucoplan; patients self-administered once-daily ZLP-AI. Primary objective was the effective ZLP-AI self-administration through Day 14, defined as investigator confirmed complete dose delivery. Satisfaction with self-injection, measured by the Self-Injection Assessment Questionnaire (SIAQ, domain scores 0–10) and safety were also assessed.*[4]

ZILBRYSQ®▼ (zilucoplan) 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.

Zilbrysq is indicated as an add-on to standard therapy for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR-) antibody positive in three approved doses: 16.6, 23 and 32.4 mg.

GL-ZL-2600006 Date of preparation: March 2026

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): Diarrhea, 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 product information in relation to other side effects, full safety profile and prescribing information SmPC.

Date of last revision: 19 March 2026.

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

For further information, contact UCB:

Global Communications
Nick Francis
T: +44 7769 307745
Nick.francis@ucb.com

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

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 more than 9,000 people in approximately 40 countries, the company generated revenue of €7.7 billion in 2025. UCB is listed on Euronext Brussels (symbol: UCB).

Forward-looking statements

This document contains forward-looking statements, including, without limitation, statements containing the words "potential", "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 guaranteeing 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 be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document.

Important factors that could result in such differences include but are not limited to: global spread and impacts of wars, pandemics and terrorism, the general geopolitical environment, climate change, 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, supply chain disruption and business continuity risks; 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 or disruptive technologies/business models, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring, retention and compliance of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, 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 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

GL-ZL-2600006 Date of preparation: March 2026

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, the public is cautioned not to place any undue reliance on such forward-looking statements. These forward-looking statements are made only as of the date of this document, and do not reflect any potential impacts from the evolving event or risk as mentioned above as well as any other adversity, unless indicated otherwise. The company continues to follow the development diligently to assess the financial significance of these events, as the case may be, to UCB.

UCB expressly disclaims any obligation to update any forward-looking statements in this document, 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.

References

1. ZILBRYSQ® EU SmPC.
2. YPSOMED. Reducing the carbon footprint of drug delivery. https://www.ypsomed.com/en/expertise/services/sustainability-services. Date accessed March 2026.
3. EMA CHMP. Zilbrysq. https://www.ema.europa.eu/en/medicines/human/summaries-opinion/zilbrysq. Date accessed March 2026.
4. Petrulis M, et al. Bioequivalence and Effectiveness of Auto-Injector-Delivered, Self-administered Zilucoplan Compared With Pre-filled Syringe. Abstract presented at: American Academy of Neurology (AAN). 2026 April 18-22; Chicago, USA.
5. 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;22:395-406.
6. YPSOMED. YpsoMate – The 2-step autoinjector. https://www.ypsomed.com/en/products/autoinjectors/ypsomate. Date accessed March 2026.
7. UCB. Reducing emissions. https://www.ucb.com/about-ucb/sustainability/environmentals-sustainability/co2e. Date accessed March 2026.
8. Punga AR, et al. Epidemiology, diagnostics, and biomarkers of autoimmune neuromuscular junction disorders. Lancet Neurol. 2022;21(2):176-88.
9. Myasthenia Gravis Foundation of America. Overview of MG. https://myasthenia.org/understanding-mg/overview-mg. Date accessed March 2026.
10. National Institute of Neurological Disorders and Stroke. 2022. Myasthenia Gravis Fact Sheet. https://www.ninds.nih.gov/myasthenia-gravis-fact-sheet. Date accessed March 2026.

GL-ZL-2600006 Date of preparation: March 2026