UCB News

UCB announces successful first-in-patient trial for galvokimig in moderate-to-severe atopic dermatitis at EADV

- **More than 60% of patients achieved at least a 75% improvement in skin lesions:** A median of 64.9% of patients treated with galvokimig versus 12.3% with placebo achieved ≥75% improvement from baseline in Eczema Area and Severity Index (EASI75) at Week 12, the primary endpoint
- **Almost half of patients achieved at least a 90% improvement in skin lesions:** A median of 46.6% of patients treated with galvokimig versus 3.5% with placebo achieved ≥90% improvement from baseline in Eczema Area and Severity Index (EASI90) at Week 12
- **Paves the way for a Phase 2b trial:** UCB will conduct further clinical trials on galvokimig in atopic dermatitis (AD), and initiation of the Phase 2b trial is expected by the end of 2025
- **Novel mechanism of action:** Galvokimig is a multi-specific antibody-based therapeutic that is designed to inhibit IL-13, IL-17A and IL-17F, with an extended half-life through albumin binding. It is designed to selectively inhibit two distinct and separate inflammatory pathways, Th2 (via IL-13) and Th17 pathways (via IL-17A/F), that are important to the chronic inflammation in AD

Brussels (Belgium), September 18, 2025 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced new 12-week efficacy and 18-week safety data from the Phase 1/2a first-in-patient trial for galvokimig, a novel multi-specific antibody-based therapeutic currently under clinical investigation for adults living with moderate-to-severe atopic dermatitis (AD). Galvokimig demonstrated clinically meaningful improvements in stringent efficacy measures for AD,[1] a common, chronic, inflammatory skin disease affecting 2–10% of adults worldwide.[2]

"The study showed that many patients achieved the stringent EASI75 and EASI90 outcomes at Week 12 with galvokimig in this early-stage trial. The data indicate the potential of galvokimig to deliver clinically meaningful improvements in larger-scale clinical trials for patients with atopic dermatitis," said Professor Jonathan Silverberg,≠ MD, PhD, MPH, Professor of Dermatology at the George Washington University School of Medicine & Health Sciences in Washington, DC. "These encouraging results provide support for targeting both Th2 and Th17 inflammatory pathways in patients with this debilitating inflammatory disease and I look forward to results from the Phase 2b clinical program."

GL-OT-2500005
Date of preparation: September 2025

In the Phase 2a trial, patients (n=47) received galvokimig (n=33) or placebo (n=14).[1] At Week 12, a median of 64.9% of patients achieved EASI75 with galvokimig versus 12.3% with placebo.[1*] Also at Week 12, a median of 46.6% of patients achieved EASI90 with galvokimig versus 3.5% with placebo.[1*]

After 18 weeks, the most common treatment-emergent adverse events (TEAEs) with galvokimig were rhinitis, nasopharyngitis, headache, dizziness and oropharyngeal pain.[1]

"Atopic dermatitis is the most common, chronic, inflammatory skin disease, affecting millions of people across the world, that can have far-reaching consequences for the everyday lives of patients and their families," said Donatello Crocetta, Head of Medical and Chief Medical Officer, UCB. "Many patients experience sub-optimal treatment responses, in part due to the complex variety of inflammatory mechanisms involved in this disease, underscoring the need for new treatment options for those living with this distressing condition."

Galvokimig is currently under clinical investigation and is not approved by any regulatory authority worldwide.

UCB's abstract on galvokimig will be presented as an oral presentation at the European Academy of Dermatology and Venereology (EADV) 2025 Congress in Paris, France, 17–20 September. The abstract complements the 19 other presentations from UCB in bimekizumab data across hidradenitis suppurativa, psoriasis, psoriatic arthritis and axial spondyloarthritis – emphasizing UCB's strong commitment to addressing unmet health needs for people living with immune-mediated inflammatory diseases.

ǂCo-author.

*NRI: non-responder imputation. All visits following discontinuation due to adverse events or lack of efficacy were treated as non-response.

Notes to Editors:

- EASI75/EASI90: A 75% and 90% or more improvement from baseline, respectively, in the Eczema Area and Severity Index (EASI).[3] The EASI assessment integrates body surface area of involvement and the intensity of lesional skin into one composite score.[4]

About atopic dermatitis

GL-OT-2500005
Date of preparation: September 2025

Atopic dermatitis (AD) is a heterogeneous disease affecting both children and adults, and is driven by a combination of chronic inflammation, epidermal dysfunction and a dysregulated skin barrier.[5,6,7] AD is characterized by recurrent skin lesions presenting as erythematous patches with exudation, blistering and crusting at early stages, and lichenification at later stages, as well as intense itch.[5] AD affects 2–10% of adults and 15–30% of children worldwide.[2] The prevalence of AD has grown by 0.98% per decade in adolescents and by 1.21% per decade in children globally.[8] AD significantly lowers the quality of life for patients and their families, being associated with sleep disturbance, anxiety, hyperactivity and depression.[9]

About the first-in-human trial

The study was a two-part, randomized, first-in-human, proof-of-concept, double-blind Phase 1/2a study of galvokimig monotherapy.[1] In part A of the study, healthy study participants received either placebo or single ascending doses of galvokimig administered by intravenous infusion or subcutaneous injection. In part B, patients with moderate-to-severe atopic dermatitis (AD) were randomized 2:1 to receive either galvokimig or placebo by intravenous infusion.[10] Patients with AD were enrolled in part B of the study and randomized 2:1 to receive intravenous galvokimig or placebo.[1] The primary endpoints in part B were ≥75% improvement from baseline in Eczema Area and Severity Index (EASI75) response rate at Week 12 and incidence of treatment-emergent adverse events (TEAEs) and serious TEAEs from baseline to Week 18.[1]

About galvokimig

Galvokimig is a multi-specific antibody-based therapeutic that is designed to inhibit IL-13, IL-17A and IL-17F, with an extended half-life through albumin binding.[1] By targeting both Th2 (via IL-13) and Th17 pathways (via IL-17A/F), combined IL-13, IL-17A and IL-17F inhibition with a single agent may improve treatment outcomes in people with atopic dermatitis.[1] The safety and efficacy of galvokimig have not been established and it is not currently approved for use in any indication by any regulatory authority worldwide.

For further information, contact UCB:

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

Corporate Communications
Laurent Schots

GL-OT-2500005
Date of preparation: September 2025

UCB News

T +32.2.559.92.64
email laurent.schots@ucb.com

Brand Communications
Adriaan Snauwaert
T +32.4.977.02.346
email adriaan.snauwaert@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 9,000 people in approximately 40 countries, the company generated revenue of €6.1 billion in 2024. UCB is listed on Euronext Brussels (symbol: UCB).

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 UCB's 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 laws and/or rules pertaining to tax and duties or the administration of such laws and/or rules, and hiring, retention and compliance of 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 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

GL-OT-2500005
Date of preparation: September 2025

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. Hunter H, et al. A first-in-patient 18-week study of galvokimig, a multispecific antibody–based therapeutic targeting interleukin (IL)-13, IL-17A and IL-17F in participants with moderate-to-severe atopic dermatitis (AD) [free communication]. EADV 2025. FCO8.
2. Lobefaro F, et al. Atopic Dermatitis: Clinical Aspects and Unmet Needs. Biomedicines. 2022;10(11):2927.
3. Silverberg JI, et al. What are the best endpoints for Eczema Area and Severity Index and Scoring Atopic Dermatitis in clinical practice? A prospective observational study. Br J Dermatol. 2021;184(5):888–95.
4. Hanifin JM, et al. The Eczema Area and Severity Index—A Practical Guide. Dermatitis. 2022;33(3):187–92.
5. Langan SM, et al. Atopic dermatitis. Lancet. 2020;396(10247):345–60.
6. Bakker D, et al. Biomarkers in atopic dermatitis. J Allergy Clin Immunol. 2023;151(5):1163–68.
7. Criado PR, et al. Update on the pathogenesis of atopic dermatitis. An Bras Dermatol. 2024;99(6):895–915.
8. Langan S, et al. Trends in eczema prevalence in children and adolescents: A Global Asthma Network Phase I Study. Clin Exp Allergy. 2023;53(3):337–52.
9. Silverberg J and Kantor R. The role of interleukins 4 and/or 13 in the pathophysiology and treatment of atopic dermatitis. Dermatol Clin. 2017;35(1):327–34.
10. ClinicalTrials.gov. NCT04643457. https://www.clinicaltrials.gov/study/NCT04643457. Last accessed: September 2025.

GL-OT-2500005
Date of preparation: September 2025