UCB News

BIMZELX[®]▼ (bimekizumab) data in moderate-to-severe plaque psoriasis at EADV showed four-year sustained remission, and potential to reduce psoriatic arthritis progression risk

- **High responses maintained over four years in nearly half of patients:** 48.9% of Week 16 PASI 0 responders sustained remission of psoriasis, achieving PASI 0 at every study visit, from Week 16 to four years*
- **Nail psoriasis improvements:** 81.8% and 82.7% of patients achieved nail matrix and nail bed mNAPSI 0 respectively, resolution of nail psoriasis, over three years – indicating potential to reduce risk of progression to psoriatic arthritis (PsA)^
- **Low occurrence of PsA symptoms:** Among patients with psoriasis and four or more risk factors for PsA at baseline, 98.1% maintained PASE <47 (no PsA symptoms) to three years≠
- **Unique dual inhibition:** BIMZELX®▼(bimekizumab) is the first and only approved medicine designed to selectively inhibit interleukin 17F (IL-17F) in addition to interleukin 17A (IL-17A)

Brussels (Belgium), September 17, 2025 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced three- and four-year data from across their Phase 3 trials for BIMZELX® (bimekizumab) in moderate-to-severe plaque psoriasis. These new data build on established evidence that bimekizumab, the first and only medicine approved to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F),[1] not only provides long-term disease control but may also prevent disease progression in psoriasis.[2,3,4]

"Achieving high disease control is a key treatment target for all patients with plaque psoriasis, as it prevents the cumulative burden of disease and potentially progression to PsA," said Richard B. Warren, Professor of Dermatology, University of Manchester and Northern Care Alliance NHS Foundation Trust. "It is therefore highly relevant to observe complete skin clearance sustained over four years in nearly half of patients who received bimekizumab, demonstrating long-term control of inflammation and the potential to improve patient outcomes."

GL-BK-2500093
Date of preparation: September 2025

Among Week 16 PASI 0 responders who entered the open-label extension (OLE) (bimekizumab [BKZ] Total group; N=503), 48.9% maintained PASI 0 at every visit from Week 16 to year four; 72.0% sustained PASI 0 at every visit except up to four visits with PASI >0–≤2, defined in this abstract as remission.[2]* In the same study, among Week 16 PASI 0 responders, 69.4% maintained body surface area (BSA) ≤1% at every visit to year four,[2]* and 81.7% maintained BSA ≤1% at every visit except up to four visits with BSA >1%–≤3%, defined in this abstract as high disease control.[2]* Separately, 81.8% (383/468) and 82.7% (386/467) of BKZ Total patients achieved nail matrix or nail bed mNAPSI 0 respectively at year three, which may contribute to reducing the risk of progression to PsA.[3,5,6]^ Of BKZ Total patients with ≥4 baseline PsA risk factors (n=68), PASE <47 (no PsA symptoms) was maintained by 98.1% of patients to three years.[4]≠ Similarly, in those with ≥4 baseline PsA risk factors (n=417), only 2.6% (0.9/100 PY) reported incidence of PsA TEAEs over four years.≠ These data support long-term bimekizumab treatment to achieve high disease control, including remission, in psoriasis and reduce risk of progression to PsA.[2,3,4]

"The presentation of this three- and four-year data is further evidence of the depth and durability of response achieved with bimekizumab treatment in psoriasis, even at highly stringent measures of disease control," said Donatello Crocetta, Head of Medical & Chief Medical Officer, UCB. "These results reinforce UCB's commitment to developing evidence-driven solutions that aim to improve care for people living with chronic inflammatory diseases and reduce the risk of disease progression."

UCB's data on bimekizumab in psoriasis will be presented at the European Academy of Dermatology and Venereology (EADV) 2025 Congress in Paris, France, 17–20 September. These abstracts are part of the 19 presentations from UCB across bimekizumab in PSO, hidradenitis suppurativa, psoriatic arthritis, axial spondyloarthritis, as well as the abstract for the investigational therapy galvokimig in atopic dermatitis.†

*mNRI-LOCF: Modified non-responder imputation last responder carried forward – patients who discontinued treatment due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; the last observation carried forward was used for other missing data. Data were pooled from the 52-week BE VIVID, 56-week BE SURE and BE READY Phase 3 trials, and their 144-week open-label extension (OLE) BE BRIGHT. Data reported here are only for patients who received continuous bimekizumab (BKZ) and entered the OLE, regardless of dosing regimen (BKZ Total).

^OC: Analyses were conducted post hoc for patients with baseline nail involvement (mNAPSI >0) using observed cases. Data are also reported for patients with psoriasis only at baseline (Psoriatic

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Arthritis Screening and Evaluation [PASE] <47 and no medical history of PsA). Data were pooled from the 52-week BE VIVID, 56-week BE SURE and BE READY Phase 3 trials, 96 weeks of their open-label extension (OLE), BE BRIGHT, and the BE RADIANT Phase 3b trial. Data reported here are only for patients who received continuous BKZ and entered the OLE, regardless of dosing regimen (BKZ Total).

≠mNRI: Patients discontinuing due to lack of efficacy or treatment-related AEs were considered non-responders; multiple imputation was used for other missing data. Proportion of patients reported from the BE RADIANT Phase 3b trial (data only available from BE RADIANT). Included patients who received BKZ 320 mg every 4 weeks (Q4W) to Week 16, then Q4W or Q8W into the open-label extension. Data are reported for patients who received continuous BKZ and entered the OLE, regardless of dosing regimen (BKZ Total).

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

Notes to Editors:

- PASI 0: Psoriasis Area and Severity Index (PASI) is a tool used to measure the severity and extent of psoriasis. PASI 0 is the same measure as PASI 100 and is considered complete skin clearance. PASI 0 at every visit except up to 2/3/4 visits with PASI >0–≤2 was defined as remission of psoriasis in the abstract[2]
- BSA: Body surface area. BSA ≤1% entails one percent or less of the body surface area is affected. BSA ≤1% at every visit except up to 2/3/4 visits with BSA >1%–≤3% was defined as high disease control in the abstract[2]
- mNAPSI 0: Patients achieving complete nail clearance in the nail matrix using the modified Nail Psoriasis Severity Index (mNAPSI)[5]
- PASE <47: The Psoriatic Arthritis Screening and Evaluation (PASE) is a questionnaire that aids the early detection of PsA and intervention,[7] helping to delay/halt progression and prevent long-term complications; PASE <47 indicates no PsA symptoms[4]

About plaque psoriasis

Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin.[8] This skin condition affects men and women of all ages and ethnicities.[9] Psoriasis signs and symptoms can vary, but may include patches of thick, red skin covered with silvery-white scales that itch or burn;

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dry, cracked skin that may bleed; and thickened, pitted or ridged nails.[10] Psoriasis affects two to three percent of the total population, or about 125 million people worldwide.[11]

About psoriatic arthritis

Psoriatic arthritis is a serious, highly heterogeneous, chronic, systemic inflammatory condition affecting both the joints and skin with a global prevalence of 0.02 percent to 0.25 percent of the population.[12] Psoriatic arthritis affects approximately 30 percent of people living with psoriasis.[13] It manifests as joint pain and stiffness, skin plaques, swollen toes and fingers (dactylitis) and inflammation of the sites where tendons or ligaments insert into the bone (enthesitis).[14] The burden on those living with PsA extends beyond physical discomfort to reduced quality of life, with comorbidities including hypertension, cardiovascular disease, anxiety and depression.[15]

About BIMZELX® ▼ (bimekizumab)

BIMZELX® is a humanized monoclonal IgG1 antibody that is designed to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), two key cytokines driving inflammatory processes.[1]

About BIMZELX® ▼ (bimekizumab) EU/EEA*

The approved indications for bimekizumab▼ in the European Union are:[1]

- **Plaque psoriasis:** Bimekizumab is indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy
- **Psoriatic arthritis:** Bimekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs)
- **Axial spondyloarthritis:** Bimekizumab is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP), and/or magnetic resonance imaging (MRI), who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs), and for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy

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- **Hidradenitis suppurativa:** Bimekizumab is indicated for the treatment of active moderate to severe hidradenitis suppurativa (HS; acne inversa) in adults with an inadequate response to conventional systemic HS therapy

The label information may differ in other countries where approved. Please check local Prescribing Information.

BIMZELX® ▼ (bimekizumab) EU/EEA* Important Safety Information

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%, 14.6%, 16.3%, 8.8% in plaque psoriasis, psoriatic arthritis, axial spondyloarthritis (axSpA) and hidradenitis suppurativa, respectively) and oral candidiasis (7.3%, 2.3%, 3.7%, 5.6% in PSO, PsA, axSpA and HS, respectively). Common adverse reactions (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, vulvovaginal mycotic infection (including vulvovaginal candidiasis), headache, rash, dermatitis and eczema, acne, injection site reactions (injection site erythema, reaction, edema, pain, swelling, hematoma), fatigue. Elderly may be more likely to experience certain adverse reactions such as oral candidiasis, dermatitis and eczema when using bimekizumab.

Bimekizumab is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients and in patients with clinically important active infections (e.g. active tuberculosis).

Bimekizumab may increase the risk of infections. Treatment with bimekizumab must not be initiated in patients with any clinically important active infection. Patients treated with bimekizumab should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops an infection the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy, treatment should be discontinued until the infection resolves. Prior to initiating treatment with bimekizumab, patients should be evaluated for tuberculosis (TB) infection. Bimekizumab should not be given in patients with active TB. Patients receiving bimekizumab should be monitored for signs and symptoms of active TB.

Cases of new or exacerbations of inflammatory bowel disease have been reported with bimekizumab. Bimekizumab is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, bimekizumab should be discontinued and appropriate medical management should be initiated.

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Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, administration of bimekizumab should be discontinued immediately and appropriate therapy initiated.

Live vaccines should not be given in patients treated with bimekizumab.

Please consult the Summary of Product Characteristics in relation to other side effects, full safety and Prescribing Information.

European SmPC date of revision: April 2025. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

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

Last accessed: September 2025.

▼ *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.*

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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 9,000 people in approximately 40 countries, the company generated revenue of €6.1 billion in 2024. UCB is

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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 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.

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Date of preparation: September 2025