

BIMZELX[®] (bimekizumab-bkzx) five-year data at AAD 2025 showed sustained skin clearance and long-term efficacy in moderate-to-severe plaque psoriasis

- **Sustained complete skin clearance over five years:** In a subset of 153 patients from the second extension of BE BRIGHT, 67.7% of patients with moderate-to-severe plaque psoriasis (PSO) treated with BIMZELX® (bimekizumab-bkzx) achieved PASI100⁺ at five years
- **Durable and broad efficacy across patient subgroups at four years:** Consistently high rates of complete or near-complete skin clearance seen at four years regardless of baseline weight or baseline cardiometabolic comorbidities such as hypertension, hyperglycemia or elevated BMI
- **High response rates in patients at risk of psoriatic arthritis at three years:** Data showed 68.7–71.6% of PSO patients at risk of developing psoriatic arthritis (PsA) achieved complete skin clearance, generally consistent with the overall treated group. Similar results were seen in all patients with PSO, including those with PsA at baseline
- **Dual inhibition:** BIMZELX® is the first and only approved medicine designed to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F)

Brussels (Belgium), March 7, 2025 – 14:00 (CET) – UCB, a global biopharmaceutical company, today announced further long-term data from the Phase 3 trials, and their open-label extensions, investigating BIMZELX® (bimekizumab-bkzx) in adults with moderate-to-severe plaque psoriasis (PSO). Dual inhibition with bimekizumab-bkzx demonstrated high efficacy and sustained clinical benefits across different adult patient populations living with this common inflammatory skin condition.^{1,2,3,4}

“A primary treatment goal for people living with psoriasis is durable, high rates of complete skin clearance. These five-year bimekizumab-bkzx results provide valuable evidence for clinical decision-making,” said Dr Andrew Blauvelt, MD, MBA, Chair, Medical Board, National Psoriasis Foundation. “The sustained complete skin clearance offers important insights into the potential of bimekizumab-bkzx’s dual inhibition to provide long-term management of this chronic inflammatory condition.”

Among patients with PSO only at baseline, who were at risk of progression to psoriatic arthritis, 68.7–71.6% achieved complete skin clearance (Psoriasis Area and Severity Index, [PASI]100) at

three years, generally consistent with the overall treated group, who achieved 72%.⁴ Similar results were seen in all patients with PSO, including those with PsA at baseline. Among the 153 US/Canadian patients who completed an open-label extension period to five years,^{*} 67.7% achieved PASI100, while 84.9% achieved PASI90.¹ In this subgroup over the five-year period, bimekizumab-bkzx was generally well tolerated with no unexpected safety findings.¹

"Psoriasis is a chronic condition that increases the risk of developing other serious health issues," said Fiona du Monceau, Executive Vice President, Head of Patient Evidence, UCB. "These five-year results highlight the robust potential of bimekizumab-bkzx in transforming patient outcomes by offering the possibility of lasting, complete skin clearance. Bimekizumab-bkzx is aiming to set a new standard for treatment success, and our belief in its innovative dual inhibition approach is reflected in our dedication to head-to-head trials, including the BE BOLD Phase 3 trial in psoriatic arthritis."

UCB's data for bimekizumab-bkzx in moderate-to-severe PSO will be presented as six posters at the 2025 American Academy of Dermatology (AAD) Annual Meeting in Orlando, Florida, U.S., 7–11 March.^{1,2,3,4,5,6} These abstracts complement other bimekizumab-bkzx data presented at AAD in hidradenitis suppurativa,^{7,8,9,10,11,12,13} psoriatic arthritis^{14,15,16} and axial spondyloarthritis,^{17,18} emphasizing UCB's leadership in addressing unmet health needs for people living with immune-mediated inflammatory diseases.

⁺PASI100: 100% improvement from baseline in Psoriasis Area and Severity Index, indicating complete skin clearance.^{1,4}

^{*}All patients received bimekizumab-bkzx every four weeks (Q4W) to Week 16, then received either Q4W or Q8W depending upon response to treatment. Receiving Q4W to Week 16, then Q8W thereafter is the approved dosing regimen (Q4W/Q8W). Results included patients receiving both Q4W/Q8W and Q4W/Q4W.

Notes to Editors:

Further detail on selected bimekizumab-bkzx data in PSO presented at AAD 2025:

- **Five-year efficacy and safety:** A US/Canadian subgroup of 153 patients* completing BE VIVID/BE SURE/BE READY and the BE BRIGHT open-label extension could enter a second 48-week extension (OLE2), where all patients received Q8W. Bimekizumab-bkzx demonstrated high rates of clinical and health-related quality of life responses, which were highly durable to Year 5.[†]

It was generally well tolerated in this patient subgroup, with no unexpected safety findings, over five years:¹

- Of the 153* patients analyzed, 75.2% and 67.7% patients achieved PASI100 at one year and five years, respectively. Similarly, 92.8% and 84.9% achieved PASI90 at one year and five years, respectively
- Over five years, in the subgroup of 153 patients*, the four most common treatment emergent adverse events (TEAEs) were: nasopharyngitis (9.7/100PY), oral candidiasis (7.6/100PY), coronavirus infection (6.1/100PY) and upper respiratory tract infection (5.8/100PY).
- **Weight stratification:** Bimekizumab-bkzx demonstrated long-term efficacy across four years regardless of patients' weight subgroup at baseline (either <90 kg or ≥90 kg):^{2*†‡}
 - Of the 420 patients analyzed who were <90 kg, 88.5%/67.4% achieved PASI90/PASI100 at four years
 - Of the 351 patients analyzed who were ≥90 kg, 83.0%/61.6% achieved PASI90/PASI100 at four years
- **Skin clearance rates in patients with cardiometabolic comorbidities:** High and durable levels of complete or near-complete skin clearance were achieved after four years of bimekizumab-bkzx treatment in 771 patients with PSO, regardless of baseline hypertension, elevated BMI, or hyperglycemia:^{3*†‡}
 - Of the 375 patients with baseline hypertension, 82.8%/59.3%, respectively, achieved PASI90/PASI100 at four years
 - Of the 344 patients with baseline elevated BMI, 82.5%/60.7%, respectively, achieved PASI90/PASI100 at four years
 - Of the 62 patients with baseline hyperglycemia, 80.4%/56.9%, respectively, achieved PASI90/PASI100 at four years
- **Patients at risk of progressing to psoriatic arthritis (PsA):** The rates of complete skin clearance (PASI100) were high after three years in bimekizumab-bkzx-treated patients with PSO and risk factors for progression to PsA, or who screened PsA-positive, consistent with the overall bimekizumab-bkzx-treated group. Outcomes were similar when the analysis was restricted to patients with only psoriasis at baseline.^{4*†‡}

*All patients received bimekizumab-bkzx every four weeks (Q4W) to Week 16, then received either Q4W or Q8W depending upon response to treatment. Receiving Q4W to Week 16, then Q8W thereafter is the approved dosing regimen (Q4W/Q8W). Results included patients receiving both Q4W/Q8W and Q4W/Q4W.

[†]Modified non-responder imputation.

[‡]Data were pooled from the 52/56-week Phase 3 trials: BE VIVID, BE SURE, BE READY, and their open-label extension (OLE) BE BRIGHT.

[‡]Data were pooled from BE VIVID, BE SURE, BE READY, the first 96 weeks of their open-label extension (OLE) BE BRIGHT, and BE RADIANT (48-week double-blinded period, plus 96-week OLE).

About Plaque Psoriasis

Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin.¹⁹ This skin condition affects men and women of all ages and ethnicities.²⁰ Psoriasis signs and symptoms can vary, but may include red patches of skin covered with silvery-white scales; dry, cracked skin that may bleed; and thickened, pitted or ridged nails.²¹ Psoriasis affects nearly three percent of the total population, or about 125 million people worldwide.²²

About Psoriatic Arthritis

Psoriatic arthritis is a serious, highly heterogeneous, chronic, systemic inflammatory condition affecting both the joints and skin with a prevalence of 0.02 percent to 0.25 percent of the population.²³ Psoriatic arthritis affects approximately 30 percent of people living with psoriasis.²⁴ 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).²⁵ 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.²⁶

About BIMZELX® (bimekizumab-bkzx)

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.²⁷ Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin.²⁷

The approved indications for BIMZELX in the U.S. are:²⁷

- **Plaque psoriasis:** BIMZELX is approved for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy

- **Psoriatic arthritis:** BIMZELX is indicated for the treatment of adult patients with active psoriatic arthritis
- **Non-radiographic axial spondyloarthritis:** BIMZELX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation
- **Ankylosing spondylitis:** BIMZELX is indicated for the treatment of adult patients with active ankylosing spondylitis
- **Hidradenitis suppurativa:** BIMZELX is indicated for the treatment of adult patients with moderate-to-severe hidradenitis suppurativa

BIMZELX U.S. IMPORTANT SAFETY INFORMATION

IMPORTANT SAFETY INFORMATION

Suicidal Ideation and Behavior

BIMZELX (bimekizumab-bkzx) may increase the risk of suicidal ideation and behavior (SI/B). A causal association between treatment with BIMZELX and increased risk of SI/B has not been definitively established. Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or SI/B. Advise monitoring for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, instruct to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.

Infections

BIMZELX may increase the risk of infections, including serious infections. Do not initiate treatment with BIMZELX in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing BIMZELX. Instruct patients to seek medical advice if signs or symptoms suggestive of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, monitor the patient closely and do not administer BIMZELX until the infection resolves.

Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX. Avoid the

use of BIMZELX in patients with active TB infection. Initiate treatment of latent TB prior to administering BIMZELX. Consider anti-TB therapy prior to initiation of BIMZELX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients for signs and symptoms of active TB during and after treatment.

Liver Biochemical Abnormalities

Elevated serum transaminases were reported in clinical trials with BIMZELX. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline, periodically during treatment with BIMZELX, and according to routine patient management. If treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected, interrupt BIMZELX until a diagnosis of liver injury is excluded. Permanently discontinue use of BIMZELX in patients with causally associated combined elevations of transaminases and bilirubin. Avoid use of BIMZELX in patients with acute liver disease or cirrhosis.

Inflammatory Bowel Disease

Cases of inflammatory bowel disease (IBD) have been reported in patients treated with IL-17 inhibitors, including BIMZELX. Avoid use of BIMZELX in patients with active IBD. During BIMZELX treatment, monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.

Immunizations

Prior to initiating therapy with BIMZELX, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with BIMZELX.

Most Common Adverse Reactions

Most common ($\geq 1\%$) adverse reactions in plaque psoriasis and hidradenitis suppurativa include upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, herpes simplex infections, acne, folliculitis, other candida infections, and fatigue.

Most common ($\geq 2\%$) adverse reactions in psoriatic arthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infections.

Most common ($\geq 2\%$) adverse reactions in non-radiographic axial spondyloarthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsillitis, transaminase increase, and urinary tract infections.

Most common ($\geq 2\%$) adverse reactions in ankylosing spondylitis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash, and vulvovaginal mycotic infection.

Please see Important Safety Information below and full U.S. Prescribing Information at <http://www.ucb-usa.com/Innovation/Products/BIMZELX>.

About BIMZELX®▼ (bimekizumab) EU/EEA*

The approved indications for bimekizumab▼ in the European Union are:²⁸

- **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
- **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 ($\geq 1/100$ 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, oedema, pain, swelling, haematoma), 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.

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: January 2025. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

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

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▼ *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 €5.3 billion in 2023. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCBUS.

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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: 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

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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.

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