UCB News

BIMZELX® (bimekizumab-bkzx) three-year rheumatology data at ACR 2025 demonstrated sustained inflammation control in psoriatic arthritis and axial spondyloarthritis

- **Sustained improvements across stringent measures of disease in patients with psoriatic arthritis (PsA):** One-year improvements were sustained to three years across strict measures of peripheral arthritis, dactylitis, enthesitis, skin psoriasis and nail psoriasis – indicating sustained inflammation control
- **Sustained clinical response to highly stringent endpoints in half of patients with axial spondyloarthritis (axSpA):** From Week 16 to three years, 50% of patients never lost ASDAS low disease activity (LDA) (<2.1) status at any assessed visit – indicating sustained inflammation control
- **First real-world findings demonstrate rapid quality of life (HRQoL) improvements in patients with PsA and axSpA:** Improvements in outcomes in routine clinical practice were reported at 24 weeks, with benefits as early as Week 2 in some patients

Brussels (Belgium), October 25, 2025 – 16:00 (CEST) – UCB, a global biopharmaceutical company, today announced new three-year data from Phase 3 trials, and their open-label extensions, investigating BIMZELX® (bimekizumab-bkzx) in adults with active psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA) (non-radiographic [nr-]axSpA and radiographic [r-]axSpA). Bimekizumab-bkzx, the first and only medicine approved to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F),[1] continued to demonstrate sustained control of inflammation and deep efficacy in patients living with PsA and axSpA.[2,3,4,5,6]

Sustained improvements across stringent measures of disease in patients with PsA[2]

"The diverse, multi-faceted nature of PsA can make it challenging to treat, as therapy should ideally address multiple disease domains," said Professor Laura Coates, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Diseases, University of Oxford, United Kingdom. "These compelling data show sustained improvements over three years across key PsA disease

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domains. This demonstrates that bimekizumab-bkzx has potential to benefit a broad range of patients, and may improve long-term inflammation control and prevent structural damage."

In patients with PsA, one-year improvements were sustained to three years across the following GRAPPA domains:* peripheral arthritis, dactylitis, enthesitis, skin psoriasis and nail psoriasis.[2] Individual domain responses were consistent between bDMARD-naïve and TNFi-IR patients.[2] Further, exposure-adjusted incidence rates per 100 patient years for uveitis and definite or probable adjudicated Inflammatory Bowel Disease (IBD) to Week 156 were 0.2 (95% confidence interval 0.1, 0.6) and 0.3 (0.1, 0.7) in BE OPTIMAL and 0 and 0.1 (0.0, 0.6) in BE COMPLETE, respectively.[2] (See Appendix for further details).

Sustained clinical response to highly stringent endpoints in half of patients with axial spondyloarthritis[4]

"In clinical practice, ASDAS LDA is an important treatment target for disease control for people living with axSpA, as it is a highly stringent measure of low disease activity," said Professor Fabian Proft, MD from Universitätsmedizin Berlin, Germany. "It is therefore meaningful that in this study of bimekizumab-bkzx, half of the patients never lost their ASDAS LDA response at any assessed visit over three years, while over three quarters of patients maintained this response over three years. This suggests long-term disease control, which is paramount in treating both nr-axSpA and r-axSpA."

A high proportion of bimekizumab-bkzx-randomized patients who achieved clinical responses at Week 16 maintained these to Week 164 across the full disease spectrum of axSpA, including nr-axSpA and r-axSpA.[4] From Week 16 through to Week 164, 50% of patients never lost their ASDAS LDA (<2.1) status at any assessed visit (MI), with a further 22.4% only losing their ASDAS LDA status at one visit, and 6.1% at two visits, respectively (MI).[4] Of the 152 patients (43.6%; NRI) who achieved ASDAS LDA at Week 16, 78.8% still achieved ASDAS LDA at Week 164 (MI).[4] (Proportion of patients who achieved ASDAS LDA at Week 16 and Week 164 in patients randomized to bimekizumab-bkzx 160 mg Q4W at baseline).[4]

Real-world findings demonstrate rapid HRQoL improvements in patients with PsA and axSpA[5,6]

Interim, post-hoc data analysis (observed case, OC) of patient-reported outcomes from the SPEAK study in routine clinical practice showed that:[5,6]

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For **bimekizumab-bkzx-treated PsA patients**, improvements in PsAID-12 total score were observed to 24 weeks, with mean (SD) change from baseline (CfB) at Week 24 of −1.9 (2.0).[5] SF-36 PCS scores improved to Week 24 (mean [SD] CfB: +4.6 [7.9]), as did PGADA scores (Mean [SD] CfB: −17.5 [23.8]).[5] At Week 2, mean (SD) change from baseline (CfB) in PsAID-12 total score and PGADA score were -0.8 (1.6) and -7.1 (19.3), respectively.[5]

For **bimekizumab-bkzx-treated nr-axSpA and r-axSpA patients**, improvements in ASAS HI score were observed to 24 weeks, with mean (SD) CfB at Week 24 of –1.6 (3.0).[6] SF-36 PCS scores improved to Week 24 (mean [SD] CfB: +5.7 [7.3]), as did PGADA scores (mean [SD] CfB: –1.0 [2.5].[6] At Week 2, mean (SD) change from baseline (CfB) in ASAS HI score and PGADA score were –0.7 (2.3) and –0.8 (2.1), respectively.[6]

"This data presented at ACR shows that bimekizumab-bkzx continues to demonstrate long-term improvement in inflammation control and deep efficacy in patients living with PsA and axSpA, and emphasizes that this effect is consistent across a spectrum of patients with these psoriatic diseases," said Donatello Crocetta, Chief Medical Officer, UCB. "This underlines the robust potential of bimekizumab-bkzx to help prevent long-term, irreversible structural damage and improve quality of life for many patients living with these debilitating rheumatic conditions."

UCB will present 16 abstracts on bimekizumab-bkzx at ACR 2025 in Chicago, Illinois, 24–29 October, across axSpA, PsA, and psoriasis. These will complement seven other presentations from UCB across their rheumatology portfolio. This data underscores UCB's ambition to be a leader in rheumatology, commitment to advancing clinical research and innovation, and focus on developing meaningful solutions across the spectrum of rheumatic diseases.

*Core domains of PsA according to GRAPPA (Group for Research and Assessment of Psoriasis and Psoriatic Arthritis) recommendations.[7]

Study methodology

PsA abstract:[2] Included patients who were randomized to subcutaneous bimekizumab-bkzx 160 mg or placebo every 4 weeks (Q4W) in BE OPTIMAL (biologic DMARD [bDMARD]-naïve patients with PsA), BE COMPLETE (patients with PsA with inadequate response or intolerance to TNF inhibitors [TNFi-IR]), BE MOBILE 1 (non-radiographic axSpA) and BE MOBILE 2 (radiographic axSpA, i.e., AS).[2] From Week 16, all placebo-randomized patients received bimekizumab-bkzx 160 mg Q4W.[2] Week 52/16 BE OPTIMAL/BE COMPLETE completers were eligible for BE VITAL open-label extension; BE MOBILE 1 and 2 Week 52 completers could enter BE MOVING.[2]

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AxSpA abstract:[4] BE MOBILE 1 (nr-axSpA) and 2 from Week 16, all patients received subcutaneous bimekizumab-bkzx 160 mg every 4 weeks. At Week 52, eligible patients could enroll in the OLE (BE MOVING).[4]

Real-world study:[5,6] SPEAK is an ongoing 52-week, multi-country, observational study in Belgium, Czechia, France, Germany, Greece, Spain and the United Kingdom.[5,6] This planned interim analysis reports data to April 2, 2025 (approx. 50% enrollment).[5,6] Adult patients with active PsA or axSpA who initiated bimekizumab-bkzx in routine clinical practice could be included if receiving treatment per label (bimekizumab-bkzx 160 mg every 4 weeks).[5,6]

Notes to Editors

- ASAS40 responder rate: Assessment in SpondyloArthritis international Society ≥40% improvement[4]
- ASAS HI: Assessment of SpondyloArthritis international Society Health Index[6]
- ASDAS LDA: axSpA Disease Activity Score (ASDAS) low disease activity (LDA; <2.1)[4,8]
- Dactylitis: Inflammation of a finger or toe[9]
- Enthesitis: Inflammation where the tendons and ligaments insert into bones[10]
- GRAPPA domains: Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA)-based treatment recommendations focus on six core domains and the PsA-related conditions, uveitis and IBD. The six core domains are: peripheral arthritis, axial disease, enthesitis, dactylitis, skin psoriasis and nail psoriasis[2]
- IBD: Inflammatory Bowel Disease
- MI: Multiple imputation[2]
- mNAPSI: Modified nail psoriasis severity index[2]
- mNRI: Modified NRI[2]
- NRI: Non-responder imputation[2]
- PASI 100: 100% improvement from baseline in Psoriasis Area and Severity Index[2]
- PGADA: Patient Global Assessment of Disease Activity[5,6]
- PsAID-12: 12-item PsA Impact of Disease questionnaire[5]
- SF-36 PCS: Short Form 36-item Health Survey Physical Component Summary[5,6]
- SJC: Swollen joint count[2]
- TNFi-IR: Inadequate response or intolerance to tumor necrosis factor inhibitors[2]
- Uveitis: Inflammation of the middle layer of the eyeball called the uvea[11]

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Appendix

Further detail from 3-year PsA data across GRAPPA domains[2]

For the majority of GRAPPA domains, 1-year improvements were sustained to 3 years across all studies.[2] These include stringent measures of disease within the disease domains, for example, complete resolution of the following:[2]

Complete resolution criteria within domains[2] Data extracted from abstract table for nail psoriasis, peripheral arthritis, enthesitis, dactylitis, skin psoriasis, nail psoriasis	**BE OPTIMAL** (bDMARD-naïve) BKZ Total (n=712)		**BE COMPLETE** (TNFi-IR) BKZ Total (n=400)	
	BKZ 160 mg Q4W Total includes patients who switched from placebo to BKZ at Week 16			
	Year 1	**Year 3**	**Year 1**	**Year 3**
Peripheral arthritis[2] Swollen joint count (SJC)=0 (mNRI) % (95% CI)	61.8 (58.2–65.5)	59.5 (55.7–63.3)	58.2 (53.2–63.1)	59.1 (54.0–64.2)

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Enthesitis[2] Complete resolution of enthesitis, LEI=0 (mNRI) in patients with enthesitis at baseline (LEI >0; BE OPTIMAL: n=213; BE COMPLETE: n=142) % (95% CI)	63.1 (56.5–69.7)	59.6 (52.7–66.5)	58.9 (50.6–67.2)	59.9 (51.4–68.4)
Dactylitis[2] Complete resolution of dactylitis, LDI=0 (NRI), in patients with dactylitis at baseline (LDI >0; BE OPTIMAL: n=89; BE COMPLETE: n=48); missing data imputed using NRI as MI was not estimable as it would not converge % (95% CI)	83.1 (75.4–90.9)	66.3 (56.5–76.1)	85.4 (75.4–95.4)	70.8 (58.0–83.7)
Skin psoriasis[2] Complete skin clearance (PASI 100) (mNRI), in patients with ≥3% body surface area affected by psoriasis at baseline (BE OPTIMAL: n=357; BE COMPLETE: n=264)	64.7 (59.6–69.8)	61.9 (56.6–67.3)	66.2 (60.3–72.1)	67.5 61.6–73.4)

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% (95% CI)				
Nail psoriasis[2] Complete resolution of nail psoriasis, mNAPSI=0 (mNRI),in patients with nail psoriasis at baseline (mNAPSI >0; BE OPTIMAL: n=400; BE COMPLETE: n=242) % (95% CI)	68.7 (64.1−73.3)	65.6 (60.5−70.6)	67.0 (61.0−73.0)	67.1 60.9−73.4)
Axial disease[2]	**Pooled BE MOBILE 1 and 2** **nr-axSpA and r-axSpA** Data were pooled for all randomized patients with nr-axSpA and r-axSpA in BE MOBILE 1 and 2			
	Any BKZ 160 mg Q4W Includes patients who switched from placebo to BKZ at Week 16 **n=586**			
	Year 1		**Year 3**	
ASAS40 responder rate (MI), % (95% CI)	62.4 (58.4, 66.4)		60.2 (56.0, 64.5)	

Adapted from Merola J. ACR. #2129566.

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.[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

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comorbidities including hypertension, cardiovascular disease, anxiety, and depression.[15] In PsA, uncontrolled active disease can lead to long-term, irreversible structural damage.[16]

About BE OPTIMAL and BE COMPLETE

BE OPTIMAL and BE COMPLETE were two Phase 3 studies evaluating the efficacy and safety of bimekizumab-bkzx in the treatment of psoriatic arthritis.[17,18] The primary endpoint in both studies was the proportion of patients reaching 50% or greater improvement in American College of Rheumatology criteria (ACR50) at Week 16.[17,18] BE OPTIMAL (bDMARD-naïve) and BE COMPLETE (TNFi-IR) assessed subcutaneous bimekizumab-bkzx 160 mg every four weeks (Q4W) in patients with PsA; both studies were placebo-controlled to Week 16, after which placebo patients switched to bimekizumab-bkzx.[17,18]

BE OPTIMAL Week 52 and BE COMPLETE Week 16 completers were eligible for BE VITAL open-label extension.[17,18]

About Axial Spondyloarthritis

Axial spondyloarthritis (axSpA), which includes both non-radiographic axSpA (nr-axSpA) and ankylosing spondylitis (AS), is a chronic, immune-mediated, inflammatory disease.[19] nr-axSpA is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.[19] axSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).[19] The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise, but not with rest.[19] Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease, and dactylitis.[19] The overall prevalence of axSpA is 0.3 percent to 1.4 percent of adults.[20,21] Approximately half of all patients with axSpA are patients with nr-axSpA.[15] axSpA onset usually occurs before the age of 45.[19] Approximately 10 to 40 percent of patients with nr-axSpA progress to ankylosing spondylitis over 2 to 10 years.[19]

About BE MOBILE 1 and BE MOBILE 2

BE MOBILE 1 and BE MOBILE 2 were two Phase 3 studies evaluating the efficacy and safety of bimekizumab-bkzx in the treatment of nr-axSpA and r-axSpA, respectively.[22] The primary endpoint in both studies was the Assessment of SpondyloArthritis international Society 40 percent (ASAS40) response at Week 16.[22] BE MOBILE 1 and BE MOBILE 2 comprised a 16-week double-blind treatment period followed by a 36-week maintenance period.[22] In BE MOBILE 1 and BE MOBILE 2, patients

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were randomized to bimekizumab-bkzx (160 mg Q4W; N=128 for BE MOBILE 1 and N=221 for BE MOBILE 2) or to placebo (N=126 for BE MOBILE 1 and N=111 for BE MOBILE 2).[22] Patients initially randomized to placebo were switched to bimekizumab-bkzx (160 mg Q4W) at Week 16.[22]

About BIMZELX® (bimekizumab-bkzx) in the U.S.
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] Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin.[1]

The approved indications for BIMZELX in the U.S. are:[1]

- **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 adults 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

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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 (≥ 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 (≥ 2%) adverse reactions in psoriatic arthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infections.

Most common (≥ 2%) adverse reactions in non-radiographic axial spondyloarthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal

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pain, myalgia, tonsillitis, transaminase increase, and urinary tract infections.

Most common (≥ 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 www.UCB-USA.com/Innovation/Products/BIMZELX.

About BIMZELX® ▼ (bimekizumab) in the European Union (EU)/European Economic Area (EEA)

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.[23]

About BIMZELX® ▼ (bimekizumab) EU/EEA*

The approved indications for bimekizumab▼ in the European Union are:[23]

- **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.

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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.

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.

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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.

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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 €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

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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.

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