UCB News

BE BOLD: BIMZELX[®] (bimekizumab-bkzx) builds on superior joint responses versus SKYRIZI® (risankizumab) at Week 16, with clinical improvements sustained through Week 24

- **Bimekizumab-bkzx sustained numerically greater ACR50 responses through all timepoints:** 54.9% receiving bimekizumab-bkzx versus 43.8% receiving risankizumab achieved ACR50 at Week 24[*†]
- **Improvements in all secondary endpoints sustained to Week 24:** Numerically greater responses without statistical significance observed for bimekizumab-bkzx across secondary endpoints sustained to Week 24
- **Complete skin clearance:** Numerically greater responses in the PASI100 exploratory endpoint as early as Week 4 sustained to Week 16, with comparable rates at Week 20 and Week 24[‡]

Brussels (Belgium), November 9, 2026 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced Week 24 data for bimekizumab-bkzx from BE BOLD, building on the study's previously reported Week 16 results, which demonstrated statistically significant superiority in ACR50 joint outcomes versus risankizumab at Week 16 in psoriatic arthritis (PsA).[1] Numerically greater rates of ACR50 were sustained through Week 24.[1] The full Week 24 findings are being presented at the 2026 ACR Convergence in Orlando, Florida, USA, November 6–11.[1] Data reported in this press release are based on the dataset included in the ACR abstract.[1]

"ACR50 is the new standard in PsA, reflecting considerable joint improvements and is known to be associated with clinically meaningful reductions in disease activity and subsequent improvements in quality of life," said Joseph F. Merola, MD MMSc, Rheumatologist, Dermatologist, President of the Psoriasis and Psoriatic Arthritis Multicenter Advancement Network, Co-President of the Group for Research in Psoriasis and Psoriatic Arthritis and President of the Rheumatologic Dermatology Society. "In the BE BOLD head-to-head trial, bimekizumab demonstrated rapid and greater ACR50 responses that were sustained to six months, in addition to delivering high rates of complete skin clearance, both of which are especially important for those living with psoriatic arthritis."

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Overall safety treatment-emergent adverse events (TEAEs) were comparable between treatments in BE BOLD, with the exception of increased rates of mild to moderate localized *Candida* infections in the bimekizumab-bkzx arm.[1] BE BOLD was not powered to compare safety.[1]

"Head-to-head trials designed to mirror clinical practice are the gold standard for comparative clinical research. The BE BOLD results help redefine treatment expectations for people living with psoriatic arthritis, reinforcing our belief that patients and clinicians can aim higher when setting treatment goals," said Donatello Crocetta, Chief Medical Officer, UCB. "This data is part of UCB's wider evidence portfolio at ACR, showing treatment with bimekizumab enables rapid and sustained clinically meaningful improvements in this chronic inflammatory disease."

The full Week 24 results from BE BOLD will be presented at ACR in an oral presentation at 10:15 ET on Tuesday 10 November. The data from BE BOLD form part of UCB's broader presence at the 2026 ACR Convergence, where a total of 18 abstracts will be presented across the UCB immunology portfolio assets in PsA, axial spondyloarthritis, rheumatoid arthritis, and systemic lupus erythematosus.

BE BOLD Week 24 results

- Week 16 data for BE BOLD, assessing bimekizumab-bkzx, the first and only medicine approved to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F),[2,3] versus the interleukin 23 inhibitor risankizumab[4] in adults living with active PsA, was first presented at the EULAR 2026 annual congress.[5] Bimekizumab met the primary endpoint for BE BOLD of superiority in ACR50 at Week 16, achieved by 49.1% receiving bimekizumab-bkzx vs 38.0% receiving risankizumab (a difference of 11.1%), with statistical significance ($p=0.0058$)[1†]
- At Week 24, ACR50 was achieved in 54.9% of those receiving bimekizumab-bkzx and 43.8% receiving risankizumab.[1*†] Higher ACR50 responses were observed with bimekizumab-bkzx at every study point, and as early as Week 4 (nominal $p<0.0001$)[1*†]
- The first ranked secondary endpoint (MDA at Week 16) was 3.4 percentage points higher with bimekizumab-bkzx ($p=0.3921$; sequential testing stopped at this point, and subsequent ranked secondary endpoints were descriptive only), with higher rates sustained to Week 24[1†]
- Numerically greater responses without statistical significance observed for bimekizumab-bkzx across secondary endpoints, encompassing joint, skin[‡] and overall disease activity, sustained to Week 24[1†]

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- At Week 4, PASI100 was achieved in 12.5% of those receiving bimekizumab-bkzx and 3.4% receiving risankizumab (nominal p<0.01).[1*†‡] At Week 16, PASI100 was achieved in 53.4% of those receiving bimekizumab-bkzx and 46.6% receiving risankizumab, without nominal significance.[1*†‡] Rates of PASI100 for bimekizumab-bkzx and risankizumab were comparable at Week 20 and Week 24 (59.7% and 59.1%, without nominal significance, at Week 24)[*†‡]
- Including all data to the cut-off, 161/277 (58.1%) bimekizumab-bkzx-treated and 152/275 (55.3%) risankizumab-treated patients had ≥1 TEAE[1]
- No new safety signals were identified in the study at Week 24.[1] Discontinuation rates due to TEAEs and serious/severe TEAEs were low in both treatment groups.[1] Fewer patients reported serious TEAEs on bimekizumab-bkzx (5 [1.8%]) than on risankizumab (9 [3.3%]).[1] One death occurred in a risankizumab-treated patient, deemed unrelated to treatment by the investigator[1]
- *Candida* infections were more frequent in bimekizumab-bkzx-treated patients (2.9%) than in risankizumab-treated patients (0.7%), as anticipated by the mechanism of action; all were mild or moderate, none were serious, systemic, or led to study discontinuation[1]

* Exploratory endpoint: nominally significant[1]

† All results are assessed with non-responder imputation (NRI): All visits following discontinuation due to adverse events or lack of efficacy were treated as non-response. Results are reported from the bimekizumab-bkzx Total group (BKZ Total), which includes those receiving bimekizumab-bkzx (n=277) 160 mg every four weeks (Q4W) in those with no or mild psoriasis (n=248), and those receiving bimekizumab-bkzx 320 mg every four weeks to Week 16 and then every eight weeks thereafter (Q4W/Q8W) in those with moderate or severe psoriasis (n=29).[1] Those in the risankizumab group (n=276) received risankizumab 150 mg at baseline, Week 4, and Week 16 regardless of whether the recipient had no or mild psoriasis (n=245), or moderate or severe psoriasis (n=31)[1]

‡ In a subgroup of people also living with psoriasis affecting at least 3% of body surface area at baseline.[1] In this subgroup: BKZ Total, n=176 [bimekizumab-bkzx 160 mg Q4W n=147; bimekizumab-bkzx 320mg Q4W/Q8W n=29]; risankizumab group, n=176.[1] At baseline, 10.5% in the bimekizumab-bkzx group and 11.2% in the risankizumab group had moderate-to-severe psoriasis, in addition to PsA.[1]

Notes to Editors

- **ACR50:** A 50% or greater improvement from baseline in American College of Rheumatology response criteria, including at least a 50% improvement in tender and swollen joint counts as well as 50% or greater improvement in three of five additional criteria (physician global,

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patient global, patient pain, function, and C-reactive protein (CRP)/erythrocyte sedimentation rate).[6] This represents a stringent efficacy outcome in psoriatic arthritis[7,8]

- **MDA:** Minimal Disease Activity (MDA), a dichotomous endpoint (i.e., either it is reached or it is not) demonstrating minimum inflammatory disease. The MDA score comprises seven relevant disease-related domains (tender/swollen joint count, skin, physical function, pain, enthesis, general patient-based evaluation), such that achieving five of the seven indicates MDA.[9] A participant in BE BOLD was considered as having MDA if five or more of the following seven criteria were fulfilled:[10]
    - Tender joint count ≤1
    - Swollen joint count ≤1
    - PASI ≤1 or BSA ≤3 (less than or equal to 3% body surface area affected)
    - PtAAP VAS ≤15 (Patient's Assessment of Arthritis Pain score ≤15: 0=no pain; 100=most severe pain)
    - PGA-PsA VAS ≤20 (Physician's Global Assessment in Psoriatic Arthritis score ≤20: 0=very good, asymptomatic, no limitation of normal activities; 100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities)
    - HAQ-DI ≤0.5 (Health Assessment Questionnaire-Disability Index score ≤0.5: degree of difficulty experienced in eight domains of daily living activities [20 questions], total score [0–3] computed from item scores, with lower scores meaning less disability)
    - Tender enthesial points ≤1
- **PASI100:** 100% improvement from baseline in Psoriasis Area and Severity Index (PASI), indicating complete skin clearance[11]

About psoriatic arthritis

Psoriatic arthritis (PsA) 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] Of people living with psoriasis, approximately 30 percent progress to also develop psoriatic arthritis.[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] In PsA, uncontrolled active disease can lead to long-term structural damage.[16]

About the BE BOLD trial

BE BOLD is a multicenter, randomized, double-blind, risankizumab-controlled, parallel-group Phase 3b study designed to evaluate the efficacy and safety of bimekizumab-bkzx in adult study participants (n=553) with active psoriatic arthritis (PsA).[1,10] The study includes adults with active PsA

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who are naïve to biologic treatments or who had previous exposure to one tumor necrosis factor-inhibitor (TNFi) with an inadequate or intolerant response.[10]
The primary endpoint in BE BOLD is ACR50 at Week 16.[10] The study has a double-blinded methodology until Week 24.[17] In the study, participants were randomized 1:1 to receive either bimekizumab-bkzx or risankizumab.[10]

For details about BE BOLD: https://clinicaltrials.gov/study/NCT06624228.

About BIMZELX®(bimekizumab) in the European Union (EU)/European Economic Area (EEA)
The approved indications for bimekizumab in the European Union are:[2]

- **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 (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis,

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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.

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

European SmPC date of revision: May 2026. 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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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. Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin, and lesional skin in HS.[3]

The approved indications for BIMZELX in the U.S. are:[3]

- **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 adequately treated. In patients with a chronic infection or a history of recurrent infection, consider

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

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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 https://www.ucb-usa.com/bimzelx-prescribing-information.pdf.

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About UCB
UCB is a global biopharmaceutical company inspired by the needs of people living with severe diseases and driven by science to make a meaningful difference in their lives. We combine our understanding of disease biology, scientific innovation and patient insights to develop differentiated medicines and solutions, with a focus on neurology, immunology and other areas of unmet medical need. Founded in Belgium in 1928, UCB has more than 10,000 employees in approximately 40 countries and 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.

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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.

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