UCB News

BIMZELX[®](bimekizumab) data at EULAR 2026 show early and sustained inflammation control can improve patient-reported outcomes and limit disease progression in PsA and axSpA

- **Early inflammation control resulted in greater improvements in patient-reported outcomes at three years:** Early responders achieving inflammation control with bimekizumab at Week 16, as measured by SJC=0 or ACR50 (PsA) and ASDAS LDA (axSpA), demonstrated sustained improvements in pain and fatigue to three years
- **Early bimekizumab treatment associated with reduced radiographic progression in PsA over three years:** Early sustained inflammation control with bimekizumab minimized progression in structural joint damage, with those with shorter disease duration, aged <45, and SJC ≤4 showing least progression
- **Substantial impact on MRI inflammation and structural lesions in nr-axSpA:** Rapid responses in MRI inflammation and structural lesions with bimekizumab in non-radiographic (nr)-axSpA sustained to two years, including no ankylosis in the sacroiliac joints, indicating inflammation control and potential tissue repair
- **Low uveitis rates across axSpA and PsA:** Inflammation control with bimekizumab over three years continued to demonstrate low rates of uveitis, a serious and common manifestation of axSpA and PsA that has significant impact on vision and quality of life

Brussels (Belgium), June 3, 2026 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced new long-term data from Phase 2/3 trials, and their open-label extensions, investigating BIMZELX®(bimekizumab) in adults with active psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA). The data for bimekizumab, a dual inhibitor of IL-17A and IL-17F,[1] are being presented at the 2026 EULAR Annual Meeting in London, UK, June 3–6.[2,3,4,5,6] PsA and axSpA are chronic inflammatory diseases with considerable impact on physical and emotional wellbeing.[7,8]

"Essential to successful management of psoriatic arthritis is achieving early and sustained inflammation control to prevent potentially irreversible long-term structural damage and to improve quality of life," said Professor Laure Gossec, from the Sorbonne University Hospital, Paris, France.

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"These new bimekizumab data show that achieving early and rapid inflammation control, as measured by meeting the stringent treatment targets ACR50 and SJC=0, was associated with greater long-term improvements in pain and fatigue. These data confirm the importance of timely intervention in optimizing management of this serious chronic inflammatory condition."

"A characteristic feature of axSpA is chronic inflammation in the sacroiliac joints and spine, often leading to long-term structural damage with potentially debilitating consequences for patients," said Professor Xenofon Baraliakos, from the Rheumazentrum Ruhrgebiet Herne, Ruhr University Bochum, Bochum, Germany. "These new data show that bimekizumab achieved significant and sustained improvements in MRI-assessed inflammation and had impact on structural lesions in the sacroiliac joints, including no development of bone damage, in patients with nr-axSpA up to two years. These findings indicate potential tissue repair and disease modification with bimekizumab treatment."

"Psoriatic arthritis and axial spondyloarthritis are serious chronic inflammatory conditions that frequently have a profoundly deleterious effect upon the routine lives of patients and their families," said Donatello Crocetta, Chief Medical Officer, UCB. "The data presented at EULAR emphasize the potential of bimekizumab, especially when used earlier, to improve patient-reported outcomes. Alongside the data for our wider scientific program, these results attest to UCB's commitment to supporting patients and clinicians by driving progress in the treatment of rheumatic disease."

Early inflammation control resulted in greater improvements in patient-reported outcomes at three years

Patients with active PsA randomized at baseline to receive bimekizumab in BE OPTIMAL or BE COMPLETE were classified as responders or non-responders based on achievement of resolution of swollen joint count (SJC=0) or ACR50 at Week 16.[2] At Week 16, 48.3% of bDMARD-naive and 45.9% of TNFi-IR patients achieved SJC=0, while 44.8% of bDMARD-naïve and 43.5% of TNFi-IR patients achieved ACR50.[2*†] In SJC=0 Week 16 responders, ≥50% improvement from baseline in pain visual analogue scale (Pain50) at three years was achieved by 64.9%/80.1% bDMARD-naïve/TNFi-IR patients; versus 47.4%/50.9% in non-responders.[2*†] Similar trends were seen at three years in the minimal clinically important difference (MCID) in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) scores: in SJC=0 Week 16 responders, 51.3%/62.3% bDMARD-naïve/TNFi-IR patients achieved FACIT-Fatigue MCID; versus 42.9%/51.6% in non-responders.[2*†] In ACR50 Week 16 responders, Pain50 at three years was achieved by 78.8%/76.5% of bDMARD-naïve/TNFi-IR patients; versus 33.3%/44.2% in non-responders.[2*†] Similar trends were seen at three years in FACIT-Fatigue MCID: In ACR50 Week 16 responders, FACIT-Fatigue MCID was achieved by

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50.8%/63.3% bDMARD-naïve/TNFi-IR patients; versus 42.3/46.7% in non-responders.[2*†] These data support early and rapid clinical response as an indicator of long-term improvements in patient-reported outcomes.[2]

Patients with axSpA randomized at baseline to receive bimekizumab in BE MOBILE 1 and 2 were classified as early responders based on achievement of ASDAS LDA at Week 16.[3] At Week 16, 45.4% of patients who later entered the open-label extension (BE MOVING) achieved ASDAS LDA.[3‡¥] Pain and fatigue were measured by total spinal pain (TSP) and Bath Ankylosing Spondylitis Disease Activity (BASDAI) Q1, respectively.[3] Of patients who achieved ASDAS LDA at Week 16, 88.0% achieved mild pain scores (TSP <4) and 87.2% achieved mild fatigue (BASDAI Q1 <4) at three years.[3‡¥] The study also assessed pain and fatigue at three years in those included in the MRI sub-study of BE MOBILE 1 and 2, and achieved MRI remission at Week 16.[3] MRI remission was defined as Spondyloarthritis Research Consortium of Canada Sacroiliac Joint (SPARCC SIJ) inflammation <2 (nr-axSpA) or Berlin spine ≤2 (r-axSpA).[3] At Week 16 in BE MOBILE 1, 65% of nr-axSpA patients who received bimekizumab achieved SPARCC SIJ <2; of those with MRI remission status available at Week 16, 76.2% and 61.9% achieved mild pain and mild fatigue scores at three years, respectively.[3‡¥] At Week 16 in BE MOBILE 2, 77.8% of r-axSpA patients who received bimekizumab achieved MRI Berlin spine ≤2; out of those with MRI remission status available at Week 16, 52.4 and 57.1% achieved mild pain and mild fatigue scores at three years, respectively.[3‡¥]

Early bimekizumab treatment associated with reduced radiographic progression in PsA over three years

In patients with PsA who were bDMARD-naïve in BE OPTIMAL and the open-label extension BE VITAL, structural progression was assessed using plain radiographs of the hands and feet, scored with the van der Heijde modified Total Sharp Score (vdH-mTSS; score range: 0–528, with higher scores indicating greater joint damage).[4‡] Of the 712 patients in the BKZ Total group, 579 had radiographs at baseline and three years in the overall radiographic set.[4‡] Radiographic progression was minimal to three years in the overall radiographic set.[4‡] Most patients in the overall radiographic set had no radiographic progression at three years, with 73.7% achieving vdH-mTSS ≤0.5 from baseline and 58.2% meeting the more stringent vdH-mTSS ≤0.0 from baseline at three years.[4‡] Higher proportions of patients who were an age of less than 45 years, shorter disease duration and lower SJC experienced no radiographic progression, indicating greater opportunity for limiting progression in structural joint damage.[4‡]

Substantial impact on MRI inflammation and structural lesions in nr-axSpA

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Of the 254 patients with nr-axSpA randomised in BE MOBILE 1, 59.8% were included in the MRI sub-study.[5] MRI Spondyloarthritis Research Consortium of Canada (SPARCC) sacroiliac joints (SIJ) inflammation score and SPARCC SIJ Structural Score (SSS: erosion, backfill, fat lesions, ankylosis) were used to assess inflammation and structural lesions, respectively.[5] Substantial mean reductions from baseline in SPARCC SIJ inflammation scores were observed at two years: change from baseline (CfB) was –6.2.[5‡] In patients with inflammation at baseline (SPARCC SIJ score ≥2), 50.9% achieved MRI remission (SPARCC SIJ score <2) at two years.[5‡] Mean reductions from baseline in erosions, evaluated using SPARCC SSS, were –1.5 at two years.[5‡] Mean increases from baseline in backfill and fat lesions were 0.7 and 0.9 at two years.[5‡] Importantly, no ankylosis of SIJ on MRI was observed, indicating no structural damage progression in this population. Together, these results indicate deep and sustained control of inflammation, no ankylosis and potential tissue repair in patients with nr-axSpA through two years.[5] This data presented at EULAR is the first two-year MRI structural lesions data assessing a biologic DMARD in nr-axSpA.

Low uveitis rates across axSpA and PsA

In this additional follow up of patients with axSpA across the pooled phase 2b/3 data, uveitis occurred in 3.9%, and the exposure-adjusted incidence rate (EAIR) per 100 patient-years was 1.2/100 patient years [95% confidence interval 0.8, 1.7]).[6] Most uveitis events were mild or moderate only.[6]

In patients with PsA, uveitis occurred in 4/1,409 (0.3%), and the EAIR was 0.1/100 patient years [95% confidence interval 0.0, 0.2]).[6] All uveitis events were mild or moderate only.[6]

These new data demonstrate the incidence of uveitis in patients with spondyloarthritis (PsA and axSpA) receiving bimekizumab over a period of three years continued to remain low.[6]

UCB's presence at EULAR 2026

These data form part of UCB's broader presence at the 2026 EULAR Annual Meeting, where a total of 27 abstracts will be presented across the UCB immunology portfolio assets in PsA, psoriasis, axial spondyloarthritis, rheumatoid arthritis, and systemic lupus erythematosus.

*mNRI: modified non-responder imputation (binary). All visits following discontinuation due to adverse events or lack of efficacy were treated as non-response, other reasons for missing data were calculated using multiple imputation (MI).[2]

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[†]PsA data reported from BE COMPLETE, BE OPTIMAL and their open-label extension (OLE), BE VITAL, for patients in the BKZ Total group (PBO/BKZ patients and BKZ-randomized patients). BE OPTIMAL (bDMARD-naïve) Week 52 and BE COMPLETE (TNFi-IR) Week 16 completers were eligible for the BE VITAL open-label extension in which all patients received subcutaneous BKZ 160 mg Q4W.[2]

[‡]OC: Data are reported as observed case (OC).

[¥]axSpA trials BE MOBILE 1 (nr-axSpA) and BE MOBILE 2 (r-axSpA) each comprised a 16-week, double-blind, placebo-controlled period and a 36-week maintenance period. All patients received subcutaneous BKZ 160 mg every 4 weeks (Q4W) from Week 16.[3,5] At Week 52, eligible patients could enter the OLE, BE MOVING.[3,5] Data presented include patients originally randomized to placebo; all patients were treated with BKZ 160 mg Q4W from Week 16.[3,5]

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% improvement in three additional criteria (physician global, patient global, patient pain, function, and CRP/erythrocyte sedimentation rate).[9] This represents a stringent efficacy outcome in psoriatic arthritis.[10,11]
- **ASDAS LDA:** axSpA Disease Activity Score (ASDAS) low disease activity (LDA; <2.1)[3,12]
- **bDMARD-naïve:** patients with psoriatic arthritis (PsA) naïve to biologics (biological disease-modifying antirheumatic drugs)
- **SJC:** Swollen joint count (SJC): the number of swollen joints in someone with PsA. SJC=0 entails absence of swollen or tender joints
- **TNFi-IR:** patients with PsA who had an inadequate response to, or were intolerant of, tumor necrosis factor inhibitors

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.[13] Of people living with psoriasis, approximately 30 percent progress to also develop psoriatic arthritis.[14] 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).[15] The burden on those living with PsA extends beyond physical discomfort to reduced

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quality of life, with comorbidities including hypertension, cardiovascular disease, anxiety, and depression.[7] In PsA, uncontrolled active disease can lead to long-term 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 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 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.[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), also known as radiographic axSpA (r-axSpA), is a chronic, immune-mediated, inflammatory disease.[19] The overall prevalence of axSpA is 0.3 percent to 1.4 percent of adults,[20,21] and disease onset usually occurs before the age of 45.[19] Approximately half of all patients with axSpA are patients with nr-axSpA, which is defined clinically by the absence of definitive X-ray evidence of structural damage to the sacroiliac joints.[19] Approximately 12% of those with nr-axSpA may progress to r-axSpA over the next 2 years.[19,22] axSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).[19] The leading symptoms of axSpA in the majority of patients are inflammatory back pain and fatigue.[19] Common clinical manifestations include acute anterior uveitis, psoriasis, inflammatory bowel disease, enthesitis, peripheral arthritis and dactylitis.[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 in the treatment of nr-axSpA and r-axSpA, respectively.[23] The primary endpoint in both studies was the Assessment of SpondyloArthritis international Society ≥40% (ASAS40) response at Week 16.[23] BE MOBILE 1 and BE MOBILE 2 comprised a 16-week double-blind placebo-controlled treatment period followed by a 36-week maintenance period.[23] In BE MOBILE 1 and BE MOBILE 2,

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patients were randomized to bimekizumab (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).[23] Patients initially randomized to placebo were switched to bimekizumab (160 mg Q4W) at Week 16.[23]

BE MOBILE 1 and BE MOBILE 2 completers were eligible to enter the BE MOVING open-label extension and receive bimekizumab for a further 112 weeks to Week 164 (three years).[3,23]

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
- **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),

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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: 30 April 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 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 € 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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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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