BIMZELX[®]▼(bimekizumab) three-year data at EULAR 2025 showed lasting efficacy and control of inflammation in psoriatic arthritis and axial spondyloarthritis

- **Sustained symptom relief in patients with psoriatic arthritis:** Achievement of the stringent ACR50 endpoint was maintained at three years by 53.2% and 55.2% of patients with psoriatic arthritis (PsA) naïve to biologics or who had an inadequate response to, or were intolerant of, tumor necrosis factor inhibitors, respectively^{†*}
- Lasting improvements in physical function across the full spectrum of patients with axial spondyloarthritis: Maintenance of ASAS40, a composite endpoint, was sustained at three years by 60.4% and 60.1% of patients with non-radiographic axial spondyloarthritis (nr-axSpA) and radiographic axial spondyloarthritis (r-axSpA), respectively^{¥*}
- Long-term inflammation control through three years:[#] New data demonstrated consistent sustainability of efficacy across stringent clinical endpoints in PsA and axSpA, showing potential to improve long-term outcomes and prevent structural damage
- **Unique dual inhibition:** BIMZELX[®] ▼ (bimekizumab) is the first and only approved medicine designed to selectively inhibit interleukin 17A (IL-17A) in addition to interleukin 17F (IL-17F)

Brussels (Belgium), June 11, 2025 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced new three-year data from Phase 3 trials, and their open-label extensions, investigating BIMZELX[®] $\mathbf{\nabla}$ (bimekizumab) in adults with active psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA). Bimekizumab, a dual inhibitor of IL-17A and IL-17F,¹ showed sustained control of inflammation and deep efficacy in patients living with PsA and axSpA,^{2,3,4,5} chronic inflammatory diseases with considerable impact on physical and emotional wellbeing.^{6,7}

Sustained symptom relief in patients with active psoriatic arthritis

"A primary treatment goal in psoriatic arthritis is sustained control of inflammation to help prevent long-term, irreversible structural damage and to improve quality of life," said Professor Laure Gossec,[‡] from the Sorbonne University Hospital, Paris, France. "These bimekizumab data are notable for their consistency across treatment-naïve and experienced patients, with elimination of swollen





joints in nearly sixty percent of patients and approximately half reaching minimal disease activity (MDA) at three years – both strong clinical responses that suggest real control of inflammation in PsA."

[#]In patients with active PsA, regardless of prior treatment experience, results from BE OPTIMAL, BE COMPLETE and their open-label extension, BE VITAL, showed that bimekizumab delivered sustained efficacy across multiple stringent clinical endpoints for up to three years.^{2,3} At three years, 59.5% and 59.1% of bDMARD-naïve and TNFi-IR patients, respectively, achieved elimination of swollen joints (SJC=0).^{+*2,3} Complete skin clearance, measured by Psoriasis Area and Severity Index [PASI]100 was maintained to three years by 61.9% and 67.5% of bDMARD-naïve and TNFi-IR patients, respectively.^{+*2,3} Minimal disease activity (MDA), a comprehensive and clinically meaningful endpoint, was sustained to three years by 52.9% and 48.8% of bDMARD-naïve and TNFi-IR patients, respectively.^{+*2,3}

Improvements in physical function across the full spectrum of patients with axial spondyloarthritis

"Long-term data, showing that patients living with axSpA can maintain high levels of clinical response, are invaluable for informed treatment decisions. It's particularly compelling to see sustained responses with bimekizumab treatment at three years with stringent outcome measures like ASAS40 and low disease activity," said Professor Xenofon Baraliakos,[‡] from the Rheumazentrum Ruhrgebiet Herne, Ruhr University Bochum, Bochum, Germany. "These endpoints are key indicators of durable inflammation control in axSpA and achieving this level of sustained disease management is likely to have a profound impact on patients' daily lives."

[#]Across patients with nr-axSpA and r-axSpA, data from two Phase 3 studies, BE MOBILE 1 and 2, and their combined open-label extension, BE MOVING, bimekizumab treatment demonstrated sustained clinical responses up to three years.⁴ Achievement of ASAS40 was sustained to three years by 60.4% and 60.1% of nr-axSpA and r-axSpA patients, respectively, while 61.8% and 59.9% of nr-axSpA and r-axSpA patients, respectively, maintained Axial Spondyloarthritis Disease Activity Score (ASDAS) low disease activity (LDA <2.1) through three years.^{¥*4}

The importance of long-term control of inflammation in patients with PsA and axSpA

"Psoriatic arthritis and axial spondyloarthritis are serious, chronic inflammatory diseases that can have a great impact in the daily lives of patients and their families. The data presented at EULAR



reinforce the role of bimekizumab to deliver deep, consistent and sustained outcomes across a spectrum of PsA and axSpA," said Donatello Crocetta, Chief Medical Officer, UCB. "These data, alongside our other EULAR data presentations of dapirolizumab pegol[§] in systemic lupus erythematosus and romosozumab in osteoporosis, reflect UCB's commitment to offering differentiated, science-driven solutions that meet the diverse and evolving needs of people living with rheumatic diseases."

Across the three-year efficacy and safety data for PsA and axSpA, bimekizumab was generally well tolerated and no new safety signals were observed.^{2,3,4} The most common treatment-emergent adverse events (TEAEs) over three years for both PsA and axSpA in these studies were SARS-CoV-2 (COVID-19) infection, nasopharyngitis and upper respiratory tract infection.^{2,3,4}

UCB will present 14 abstracts on PsA and axSpA at EULAR 2025 in Barcelona, Spain, 11–14 June, and will complement other presentations from UCB in systemic lupus erythematosus and osteoporosis. These data, together with a dedication to advancing clinical research – including the ongoing head-to-head Phase 3 BE BOLD trial in psoriatic arthritis – underscore UCB's ambition to be a leader in rheumatology, commitment to advancing innovation and focus on providing meaningful solutions across the spectrum of rheumatic diseases.

[†]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.^{2,3}

*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).^{2,3,4}

[¥]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 16.⁴ At Week 52, eligible patients could enter the OLE, BE MOVING.⁴ Of 586 randomized patients with axSpA (nr-axSpA: 254; r-axSpA: 332), 494 (84.3%) patients entered the OLE at Week 52.⁴ Data presented include patients originally randomized to placebo; all patients were treated with BKZ 160 mg Q4W from Week 16.⁴

[‡]co-author.





[§]Dapirolizumab pegol is an investigational drug and is not approved for use in systemic lupus erythematosus by any regulatory authority worldwide.

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).⁸ This represents a stringent efficacy outcome in PsA^{9,10}
- ASAS40: Assessment of SpondyloArthritis international Society 40%, a composite endpoint covering a core set of domains that should be assessed in axSpA patients. This core set of domains includes physical function, morning stiffness, patient global assessment, and pain. In order to meet an ASAS40 response, three of the four domains should improve by at least 40% and a minimum of two units on a scale of one to ten. In the remaining domain, there should be no worsening at all¹¹
- TNFi-inadequate response (TNFi-IR): Patients with PsA who experience prior inadequate response or intolerance to tumor necrosis factor inhibitors³
- bDMARD-naïve: Patients who had not previously taken a biologic disease-modifying antirheumatic drug (bDMARD)²

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 comorbidities including hypertension, cardiovascular disease, anxiety, and depression.⁶ In PsA, uncontrolled active disease can lead to long-term, irreversible structural damage.¹⁵

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.^{9,16} 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.^{9,16} 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.^{9,16}

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

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.⁷ nr-axSpA is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.⁷ axSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).⁷ The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise, but not with rest.⁷ Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease, and dactylitis.⁷ The overall prevalence of axSpA is 0.3 percent to 1.4 percent of adults.^{18,19} Approximately half of all patients with axSpA are patients with nr-axSpA.⁷ axSpA onset usually occurs before the age of 45.⁷ Approximately 10 to 40 percent of patients with nr-axSpA progress to ankylosing spondylitis over 2 to 10 years.⁷

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.²⁰ The primary endpoint in both studies was the Assessment of SpondyloArthritis international Society 40 percent (ASAS40) response at Week 16.²⁰ BE MOBILE 1 and BE MOBILE 2 comprised a 16-week double-blind treatment period followed by a 36-week maintenance period.²⁰ In BE MOBILE 1 and BE MOBILE 2, 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).²⁰ Patients initially randomized to placebo were switched to bimekizumab (160 mg Q4W) at Week 16.²⁰

About BIMZELX[®] ▼ (bimekizumab)

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





About BIMZELX[®] ▼ (bimekizumab) EU/EEA*

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

- **Plaque psoriasis:** Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy
- **Psoriatic arthritis:** Bimekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs)
- **Axial spondyloarthritis:** Bimekizumab is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP), and/or magnetic resonance imaging (MRI), who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs), and for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy
- **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, 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: April 2025. <u>https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf</u>

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

Last accessed: May 2025.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.





For further information, contact UCB:

Investor Relations Antje Witte T +32.2.559.94.14 email antje.witte@ucb.com

Corporate Communications Laurent Schots T +32.2.559.92.64 email <u>laurent.schots@ucb.com</u>

Brand Communications Amy Cheshire T +44 7786 743 577 email <u>amy.cheshire@ucb.com</u>

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 \in 5.3 billion in 2023. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCBUSA.

Forward looking statements

This document contains forward-looking statements, including, without limitation, statements containing the words "potential", "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guaranteeing future performance and are subject to known and unknown risks, uncertainties, and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document. Important factors that could result in such differences include but are not limited to: global spread and impacts of wars, pandemics and terrorism, the general geopolitical environment, climate change, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues, supply chain disruption and business continuity risks; potential or actual data security and data privacy breaches, or disruptions of our 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 tax laws or the administration of such laws, and hiring, retention and compliance of its 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.





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Given these uncertainties, the public is cautioned not to place any undue reliance on such forward-looking statements. These forwardlooking 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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