UCB News

BIMZELX® ▼(bimekizumab) superior to SKYRIZI® (risankizumab) in BE BOLD: first head-to-head study in active psoriatic arthritis (PsA) to demonstrate superiority in ACR50

- **Primary endpoint showing superiority met:** Bimekizumab achieved statistically significant superiority over risankizumab in reducing disease activity, as measured by the stringent ACR50 endpoint, at Week 16 in adults living with active psoriatic arthritis
- **Landmark psoriatic arthritis (PsA) study:** Bimekizumab is the first licensed biologic therapy to demonstrate superiority in psoriatic arthritis over an IL-23 inhibitor
- **Fourth bimekizumab study showing superiority:** BE BOLD is the fourth head-to-head study demonstrating superiority in the bimekizumab clinical trial program across psoriatic disease, and the first conducted in PsA

Brussels (Belgium), March 11, 2026 – 07:00 (CET) – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, today announced positive topline data from the BE BOLD trial assessing BIMZELX®▼ (bimekizumab) versus SKYRIZI® (risankizumab) in adults living with active psoriatic arthritis (PsA). Bimekizumab, the first and only approved medicine to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), demonstrated statistically significant superiority in the ACR50 primary efficacy endpoint at Week 16. Treatment with bimekizumab was generally well tolerated, with no new safety signals observed to Week 16.

"Our landmark BE BOLD study provides the first head-to-head evidence of superiority versus an IL-23 inhibitor in psoriatic arthritis. These topline results reinforce bimekizumab's potential to deliver clinically meaningful improvements using the stringent ACR50 measure of disease activity, indicating more complete control of joint inflammation," said Emmanuel Caeymaex, Executive Vice President, Head of Patient Evidence, UCB. "BE BOLD represents the fourth head-to-head study demonstrating bimekizumab superiority, supporting physicians to make informed treatment decisions and advancing our ambitions to raise the standard of care for people living with psoriatic disease."

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The results of BE BOLD add to the breadth of data for bimekizumab across a range of immune-mediated inflammatory diseases. UCB plans to submit the full BE BOLD results to a forthcoming international congress.

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).[1] This represents a stringent efficacy outcome in psoriatic arthritis.[2,3]

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.[4] Of people living with psoriasis, approximately 30 percent progress to also develop psoriatic arthritis.[5] 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).[6] 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.[7] In PsA, uncontrolled active disease can lead to long-term structural damage.[8]

About the BE BOLD trial

BE BOLD is a multicenter, randomized, double-blind, risankizumab-controlled, parallel-group study designed to evaluate the efficacy and safety of bimekizumab in adult study participants (n=553) with active psoriatic arthritis (PsA).[9] The study includes adults with active PsA who are naïve to biologic treatments or who had previous exposure to one tumor necrosis factor-inhibitor (TNFi) with an inadequate or intolerant response.[9]

The primary endpoint in BE BOLD is ACR50 at Week 16.[9] The study has a double-blinded methodology until Week 24.[10] In the study, participants were randomized 1:1 to receive either bimekizumab or risankizumab.[10]

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

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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.[11]

About BIMZELX® ▼ (bimekizumab) EU/EEA*

The approved indications for bimekizumab▼ in the European Union are:[11]

- **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: 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.*

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.[12] Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin.[12]

The approved indications for BIMZELX in the U.S. are:[12]

- **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 full U.S. Prescribing Information at www.UCB-USA.com/Innovation/Products/BIMZELX.

For further information, contact UCB:

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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 more than 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.
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

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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. 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.

UCB expressly disclaims any obligation to update any forward-looking statements in this document, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

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