UCB News

BIMZELX® (bimekizumab-bkzx) data in hidradenitis suppurativa showed improvements in pain and resolution of draining tunnels sustained to three years

- **Resolution of draining tunnels sustained to three years:** Of patients who had at least one draining tunnel at baseline, 48.2% had none at one year, and 62.9% at three years* – indicating sustained inflammation control in these lesions
- **Zero draining tunnel count sustained to three years:** Of patients with no draining tunnels at baseline, 87.8% still had none at one year, and 90.8% at three years* – indicating sustained inflammation control in these lesions
- **Clinically meaningful improvements in skin pain sustained to three years:** At baseline, only 10.0% of patients reported no/mild skin pain. This increased to 51.7% at one year and 65.8% at three years*

Brussels (Belgium), October 31, 2025 – 18:00 (CEST) – UCB, a global biopharmaceutical company, today announced three-year data from the BE HEARD trials^ for BIMZELX[®] (bimekizumab-bkzx) in moderate to severe hidradenitis suppurativa (HS). Bimekizumab-bkzx, the first and only medicine approved to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F),[1] demonstrated improvements in skin pain and resolution of draining tunnels, sustained to three years.[2,3,4,5]

"Resolution of draining tunnels and abscesses is key for patients with HS because of the huge impact these lesions have on patients' lives," said Professor Steven Daveluy, M.D., Program Director, Wayne State University, Detroit, US. "These new data, showing high rates of resolution of these painful lesions to three years, demonstrate the sustained inflammation control provided by bimekizumab and suggest the possibility of reducing the structural damage frequently seen with HS which can be so devastating for patients."

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"These results for bimekizumab show meaningful improvements in inflammatory lesions and skin pain to three years, and offer a valuable perspective on its deep and sustained efficacy for patients with HS," said Donatello Crocetta, Chief Medical Officer, UCB. "Our research presented at SHSA underscores UCB's commitment to providing long-term data addressing key clinical features of chronic inflammatory conditions with a high unmet need."

Of patients who had at least one draining tunnel at baseline (n=425), 48.2% (205/425) had none at one year, and 62.9% (183/291) at three years.[2]* In the same analysis of patients who had at least one abscess at baseline (n=381), 75.3% (287/381) had none at one year, and 83.5% (203/243) at three years.[2]* In a second analysis of patients with no draining tunnels at baseline (n=131), 87.8% (115/131) still had none at one year, and 90.8% (69/76) at three years.[3]* In a third analysis, at baseline 10.0% (55/551) of patients reported no/mild skin pain, based on HSSQ skin pain item scores; at year one/three, the proportion of patients reporting no/mild skin pain increased to 51.7% (287/555) and 65.8% (237/360), respectively.[4]*

UCB will present six abstracts on bimekizumab-bkzx in HS at the Symposium on Hidradenitis Suppurativa Advances (SHSA) 2025 congress in Nashville, Tennessee, October 31 to November 2, 2025. These data emphasize UCB's strength in providing rigorous, insightful clinical research, and meaningful solutions for this serious chronic disease.

*OC: Data are reported as observed case (OC). The data reported are from an observational, open-label study. Patients completing the 48-week BE HEARD I & II studies could enroll in BE HEARD EXT and receive open-label bimekizumab (BKZ) 320 mg every 2 weeks (Q2W) or Q4W based on HiSCR90 response averaged from Weeks 36, 40 and 44.[6] Data are reported for patients randomized to BKZ from baseline in BE HEARD I & II who entered BE HEARD EXT (BKZ Total group, n=556) at Week 48. Only patients who entered the third year are included.[2,3,4,5] The approved dosing regimen is bimekizumab 320mg Q2W to Week 16 and then 320mg Q4W thereafter.[1] Results included patients receiving both Q2W and Q4W after Week 48. All patients who continued in the trial after Week 48 were subsequently switched to Q4W by the end of year three. For safety outcomes, data are reported for patients who received one or more doses of BKZ across BE HEARD I & II and BE HEARD EXT (total of three years).

Notes to Editors

- Draining tunnels: These are painful, pus-discharging tunnels under the skin resulting from long-term inflammation, frequently leading to scarring[7]

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- HSSQ: Skin pain severity was assessed using the skin pain item of the HS Symptom Questionnaire (HSSQ), scored 0–10. No/mild: 0–2; moderate: 3–5; severe/very severe: 6–10[4]
- HiSCR50/HiSCR75/HiSCR90/HiSCR100: These are defined as at least a 50%/75%/90%/100% reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count[6]

About hidradenitis suppurativa

Hidradenitis suppurativa (HS) is a chronic, painful and potentially debilitating inflammatory skin disease that is associated with systemic manifestations.[7,8] The main symptoms are nodules, abscesses and pus discharging draining tunnels (or sinus tracts leading out of the skin) which typically occur in the armpits, groin and buttocks.[7,8] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[7,8] HS develops in early adulthood and affects approximately one percent of the population in most studied countries.[7,8]

^About BE HEARD trials

The efficacy and safety profile of bimekizumab were evaluated in adult patients with moderate to severe hidradenitis suppurativa (HS) in two multicenter, randomized, double-blind, placebo-controlled Phase 3 studies (BE HEARD I and BE HEARD II).[9] The two studies had a combined enrollment of 1,014 participants.[9] In each study, patients were randomized 2:2:2:1 (initial [16 weeks]/maintenance [32 weeks]) to bimekizumab 320 mg every two weeks, four weeks or a combination (BKZ Q2W/Q2W, BKZ Q2W/Q4W, BKZ Q4W/Q4W or placebo/BKZ Q2W).[9] Receiving BKZ Q2W to Week 16, then Q4W thereafter is the approved dosing regimen (Q2W/Q4W) for the treatment of HS.

Patients who completed Week 48 could enroll in the open-label extension.[6] Of 1,014 total patients, 556 patients randomized at baseline to bimekizumab in BE HEARD I and II completed Week 48 and entered the open-label extension study.[2]

For details about BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195.

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

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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.[10]

About BIMZELX® ▼ (bimekizumab) EU/EEA*

The approved indications for bimekizumab▼ in the European Union are:[10]

- **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), 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.

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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.*

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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.[1] Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin.[1]

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

- **Plaque psoriasis:** BIMZELX is approved for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
- **Psoriatic arthritis:** BIMZELX is indicated for the treatment of adult patients with active psoriatic arthritis
- **Non-radiographic axial spondyloarthritis:** BIMZELX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation
- **Ankylosing spondylitis:** BIMZELX is indicated for the treatment of adult patients with active ankylosing spondylitis
- **Hidradenitis suppurativa:** BIMZELX is indicated for the treatment of adults with moderate to severe hidradenitis suppurativa

BIMZELX U.S. IMPORTANT SAFETY INFORMATION

IMPORTANT SAFETY INFORMATION

Suicidal Ideation and Behavior

BIMZELX (bimekizumab-bkzx) may increase the risk of suicidal ideation and behavior (SI/B). A causal association between treatment with BIMZELX and increased risk of SI/B has not been definitively established. Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or SI/B. Advise monitoring for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, instruct to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.

Infections

BIMZELX may increase the risk of infections, including serious infections. Do not initiate treatment with BIMZELX in patients with any clinically important active infection until the infection resolves or is 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

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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.

Most common (≥ 2%) adverse reactions in ankylosing spondylitis include upper respiratory tract

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infections, oral candidiasis, headache, diarrhea, injection site pain, rash, and vulvovaginal mycotic infection.

Please see Important Safety Information below and full U.S. Prescribing Information at www.UCB-USA.com/Innovation/Products/BIMZELX.

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About UCB
UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With approximately 9,000 people in approximately 40 countries, the company generated revenue of €6.1 billion in 2024. UCB is listed on Euronext Brussels (symbol: UCB).

Forward looking statements
This document contains forward-looking statements, including, without limitation, statements containing the words "potential", "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guaranteeing future performance and are subject to known and unknown risks, uncertainties, and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document.

Important factors that could result in such differences include but are not limited to: global spread and impacts of wars, pandemics and terrorism, the general geopolitical environment, climate change, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues, supply chain disruption and business continuity risks; potential or actual data security and data privacy breaches, or disruptions of UCB's information technology systems,

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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.

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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