UCB News

UCB announces new BIMZELX[®] (bimekizumab-bkzx) data at AAD showing durable symptom control throughout three years in hidradenitis suppurativa

- **Symptom control throughout three years:** 86.1% of people living with moderate to severe hidradenitis suppurativa (HS) treated with bimekizumab-bkzx had no acute exacerbation of symptoms, known as 'flares', to three years in a post hoc analysis*
- **Improved outcomes with earlier treatment:** Of those treated with bimekizumab-bkzx, a post hoc analysis showed shorter disease duration and lower severity yielded improved outcomes at three years*
- **Consistency across patient populations:** Bimekizumab-bkzx demonstrated efficacy improvements over three years across HS population subgroups, including BMI, age, disease duration, sex, and disease severity in a post hoc analysis *

Brussels (Belgium), March 27, 2026 – 15:00 (CET) – UCB, a global biopharmaceutical company, today announced data for bimekizumab-bkzx in active moderate to severe hidradenitis suppurativa (HS) at the 2026 American Academy of Dermatology (AAD) Annual Meeting in Denver, US, on March 27–31. These data from three post hoc analyses of the BE HEARD trials^ show the potential of bimekizumab-bkzx to provide durable symptom relief for people living with this challenging dermatological condition.[1,2,3,4]

"Over eighty percent of people living with HS experience periodic worsening of symptoms, or flares, at least once a month, which can impose an enormous strain on their lives," said Dr. Steven Daveluy, Department of Dermatology, Wayne State University School of Medicine, Detroit, US. "The data at AAD showed that nearly ninety percent of patients treated with bimekizumab had no acute exacerbations of symptoms at scheduled visits for up to three years, indicating its potential ability to provide durable, long-term control."

"At UCB, we are committed to generating long-term evidence that helps advance care in moderate to severe HS," said Donatello Crocetta, Chief Medical Officer, UCB. "These data suggest improved outcomes for those who start treatment earlier and with lower baseline severity, reinforcing the window of opportunity in HS and underscoring the importance of earlier diagnosis and treatment."

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The 3 Year data reported for the BE HEARD extension trial (BE HEARD EXT) includes the bimekizumab-bkzx total patients who completed Week 148 (N=367).* Of those who entered BE HEARD EXT, the cumulative proportion who were free of acute exacerbation of symptoms (defined as a ≥25% increase in abscess and inflammatory nodule (AN) count versus baseline with an absolute increase in AN count of ≥2) at any scheduled clinic visit up to three years was 86.1% (316/367).[1*] In a separate post hoc analysis, Hidradenitis Suppurativa Clinical Response (HiSCR) response at three years was assessed for patients in the lowest disease duration quartile (<2.38 years since HS diagnosis) with moderate baseline disease severity (as defined by Hurley Stage II) versus highest disease duration quartile (≥10.74 years since HS diagnosis) with severe baseline disease severity (as defined by Hurley Stage III).[2*] At three years, HiSCR90/100 was achieved by 74.1% (43/58)/62.1% (36/58), respectively, in those with the lowest disease duration and moderate baseline HS, versus 51.5% (17/33)/33.3% (11/33), respectively, with the highest disease duration and severe baseline HS.[2*] In a third post hoc analysis, HiSCR response at three years was assessed in subgroups: age (<35 years vs ≥35 years), sex, median disease duration at baseline (<5.02, ≥5.02 years), severity assessed by Hurley Stage (II, III), body mass index (<30 kg/m^2, 30–<35 kg/m^2, ≥35 kg/m^2).[3*] Bimekizumab-bkzx was associated with efficacy improvements in all subgroups, with improvements in clinical response maintained over three years.[3*]

These data form part of UCB's broader presence at the 2026 AAD Annual Meeting, where a total of eleven abstracts will be presented across the bimekizumab-bkzx portfolio in hidradenitis suppurativa, plaque psoriasis, psoriatic arthritis, and axial spondyloarthritis.

*OC: Data are reported as observed case (OC). Patients completing the 48-week BE HEARD I & II studies could enroll in BE HEARD EXT and receive open-label bimekizumab-bkzx (BKZ) 320 mg every 2 weeks (Q2W) or Q4W based on HiSCR90 response averaged from Weeks 36, 40, and 44.[5] Patients receiving BKZ 320 mg Q4W in BE HEARD EXT who could not sustain an average improvement from baseline in AN count of >90% over any 8-week period or achieve >75% improvement from baseline in AN count at any single visit, could have their dose increased to Q2W at investigator discretion. Following approval of a protocol amendment in the third year, all BE HEARD EXT patients received BKZ Q4W. Data based on patients randomized to BKZ from baseline in BE HEARD I & II who completed BE HEARD EXT to Week 148 (BKZ Total group, N=367).[1,2,3,4] The approved dosing regimen for moderate-to-severe HS is bimekizumab-bkzx 320 mg by subcutaneous injection Q2W to Week 16 and then 320 mg Q4W thereafter.[6]

Notes to Editors

GL-BK-2600006
Date of preparation: March 2026

- **Abscesses:** Tender but fluctuating masses with a diameter of >10 mm, surrounded by an erythematous area; the middle of an abscess contains pus[7]
- **Draining tunnels:** These are painful, pus-discharging tunnels under the skin resulting from long-term inflammation, frequently leading to scarring[8]
- **Flare:** A flare was defined at a given visit as ≥25% increase in abscess and inflammatory nodule (AN) count versus baseline with an absolute increase in AN count of ≥2[1]
- **HiSCR50/HiSCR75/HiSCR90/HiSCR100:** These are defined as at least 50%/75%/90% or 100% improvement in the Hidradenitis Suppurativa Clinical Response (HiSCR) score. The percentage improvement in HiSCR score is percentage reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count[9]
- **Hurley Stage I/II/III:** The Hurley staging system is a clinical tool for assessing the severity of HS.[10] Stage I disease is localized and includes the formation of single or multiple abscesses, without sinus tracts and scarring.[10] Stage II is characterized by recurrent abscesses, with sinus tract formation and scarring, occurring as either single lesions or multiple, widely separated lesions.[10] Stage III includes diffuse or nearly diffuse involvement of the affected region, with multiple interconnected tracts and abscesses across the entire area[10]
- **Inflammatory nodules:** Raised, three-dimensional, round, infiltrated lesions with a diameter of >10 mm[7]

^About BE HEARD trials

The efficacy and safety profile of bimekizumab-bkzx 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).[11] The primary endpoint data of BE HEARD I and BE HEARD II was HiSCR50 at Week 16.[11] The two studies had a combined enrollment of 1,014 participants.[11] In each study, patients were randomized 2:2:2:1 (initial [16 weeks]/maintenance [32 weeks]) to bimekizumab-bkzx 320 mg every two weeks, four weeks or a combination (BKZ Q2W/Q2W, BKZ Q2W/Q4W, BKZ Q4W/Q4W or placebo/BKZ Q2W).[11] Receiving BKZ Q2W to Week 16, then Q4W thereafter is the approved dosing regimen (Q2W/Q4W) for the treatment of moderate-to-severe HS.[12]

Patients who completed Week 48 could enroll in the open-label extension.[5] Of 1,014 total patients, 556 who were randomized at baseline to bimekizumab-bkzx in BE HEARD I and II completed Week 48 and entered the open-label extension study.[5]

GL-BK-2600006
Date of preparation: March 2026

Flare was a secondary endpoint in the BE HEARD II trial. At week 16, no significant differences in flares were detected between the treatment and placebo groups.[11] Flare was not a secondary endpoint in the BE HEARD I trial.[11]

These data were post hoc analyses and should be interpreted with caution as the analyses were not prespecified in the original protocols.

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

About hidradenitis suppurativa

Hidradenitis suppurativa (HS) is a chronic, painful and potentially debilitating inflammatory skin disease that is associated with systemic manifestations.[8,10] 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.[8,10] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[8,10] HS develops in early adulthood and affects approximately one percent of the population in most studied countries.[8,10]

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.[12]

About BIMZELX® ▼(bimekizumab) EU/EEA*

The approved indications for bimekizumab▼ in the European Union are:[12]

- **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)

GL-BK-2600006
Date of preparation: March 2026

- **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.

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.

GL-BK-2600006
Date of preparation: March 2026

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.

Last accessed: March 2026.

▼ *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.[6] Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin, and lesional skin in HS.[6]

The approved indications for BIMZELX in the U.S. are:[6]

- **Plaque psoriasis:** BIMZELX is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy

GL-BK-2600006
Date of preparation: March 2026

- **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 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

GL-BK-2600006
Date of preparation: March 2026

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 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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GL-BK-2600006
Date of preparation: March 2026

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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, 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

GL-BK-2600006
Date of preparation: March 2026

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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