UCB News

# BIMZELX®▼(bimekizumab) two-year data at EHSF 2025 demonstrate sustained disease control in hidradenitis suppurativa (HS)

- **Reduced disease severity:** After two years of BIMZELX®▼ (bimekizumab) treatment, 53.1% (237/446) of patients had mild disease compared to 0.0% at baseline
- **Sustained disease control:** At two years, 83.4% (372/446) of patients with hidradenitis suppurativa (HS) remained flare-free, while 86.9% (265/305) of HiSCR75* responders to bimekizumab at 48 weeks maintained this response
- **Unique dual inhibition:** BIMZELX® is the first and only approved medicine designed to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F)

**Brussels (Belgium), February 12, 2025 – 07:00 (CET)** – UCB, a global biopharmaceutical company, today announced long-term data from the BE HEARD^ trials for BIMZELX®▼ (bimekizumab) in moderate to severe hidradenitis suppurativa (HS). These two-year data, building on the established efficacy profile of bimekizumab in HS, showcase that its unique dual inhibition offers a durable treatment option for this challenging, chronic skin condition.[1,2,3,4,5]

"For people living with HS, draining tunnels associated with moderate and severe disease can be incredibly distressing and painful – often derailing daily life," said Professor Christos C. Zouboulis, President of the European Hidradenitis Suppurativa Foundation (EHSF) e.V., Director of the Departments of Dermatology, Venereology, Allergology and Immunology, Städtisches Klinikum Dessau, and Founding Professor of Dermatology and Venereology at the Brandenburg Medical School, Germany. "These new, specific two-year data demonstrate bimekizumab's ability to provide sustained disease control, meaning a shift towards mild disease characterized by the absence of draining tunnels, offering hope for long-term disease management and reduced burden for HS patients."

Among patients who achieved response to bimekizumab at one year, over 85.0% maintained response across a range of endpoints to two years (percentage responders at Week 48 through Week 96: 90.0% (332/369) maintained HiSCR50; 86.9% (265/305) maintained HiSCR75; 86.0% (234/272) maintained DLQI MCID).[1] Improvements in disease severity, as measured by IHS4ⁿ (a validated clinician-rated tool), were demonstrated with the majority of patients shifting over two

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years from severe to mild and moderate disease (baseline to two-year data: mild: 0.0% to 53.1% (237/446); moderate:12.6% (70/556) to 26.5% (118/446); severe: 87.4% (486/556) to 20.4% (91/446).[2] The mean (SD) draining tunnel count also decreased over two years.[2] Additionally, patients reported that gradual improvement to no/mild severity of symptoms translated to improved health-related quality of life over two years.[3] This highlights the impact of bimekizumab in providing durable control of symptoms which contribute to the profound negative effects of HS on patients' quality of life.[3,6]

"As the first presentation of bimekizumab data this year, we are thrilled it demonstrates the durability of response in HS treatment," said Fiona du Monceau, Executive Vice President, Head of Patient Evidence, UCB. "Sustained flare control, maintenance of response and improvement across multiple measures of disease severity through two years show how bimekizumab can transform outcomes for people living with HS. These data confirm our commitment to improving the lives of those living with HS, now and into the future."

Abstracts will be presented as two posters and three oral presentations today, at the 14th Conference of the European Hidradenitis Suppurativa Foundation (EHSF) in Vilnius, Lithuania.[1,2,3,4,5]

^Further results from BE HEARD EXT evaluating the efficacy and safety profile of bimekizumab will be presented later this year.

*HiSCR75 is defined as at least a 75% reduction from baseline in the total abscess and inflammatory nodule count, with no increase from baseline in abscess and inflammatory nodule or draining tunnel count.[7]

ηIHS4 is a validated clinician-rated tool that assigns different weights to the number of inflammatory nodules, abscesses and draining tunnels (DTs).[2] The presence of a draining tunnel is sufficient to classify an HS patient as at least moderate.[8]

## Notes to Editors:

### Bimekizumab two-year data in HS presented at EHSF 2025:

Data were pooled from the BE HEARD I&II studies and BE HEARD EXT. Week 48 completers could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or every 4 weeks (Q4W) based on ≥90% HS Clinical Response (HiSCR90; averaged from BE HEARD I&II Weeks 36, 40 and 44). The approved dosing regimen is 320 mg Q2W up to Week 16 and Q4W thereafter.[9] Patients

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randomized to receive BKZ from baseline in BE HEARD I&II and who entered BE HEARD EXT were included (BKZ Total group).[4] Of these 556 patients, 446 patients in the open-label extension study completed Week 96 (two years).[10]

- **IHS4:** Patients demonstrated improvements in disease severity as measured by the International Hidradenitis Suppurativa Severity Score System (IHS4), a validated clinician-rated tool that assigns different weights to the number of inflammatory nodules, abscesses and draining tunnels (DTs).[2] The proportion of patients in the severe (≥11 points) IHS4 stage decreased from 87.4% (486/556) at baseline to 20.4% (91/446) at Week 96[2†]
- **IHS4-75 and IHS4-90:** IHS4-75 and IHS4-90 are stringent clinical scores based on an improvement of at least 75% and 90%, respectively, in IHS4 total score from baseline.[4] The proportion of patients who achieved IHS4-75 and IHS4-90 at Week 96 was 71.7% (320/446) and 50.9% (227/446), respectively[4†]
- **Impact on flares:** The low rate of flares seen with bimekizumab treatment at Week 48 was maintained to two years, with 83.4% (372/446) of patients remaining flare-free at Week 96.[5] A flare was defined as ≥25% increase in abscess and inflammatory nodule (AN) count with an absolute increase in AN count of ≥2 relative to baseline[5†]
- **Draining tunnels (DTs):** The mean (SD) DT count for patients decreased from 3.8 (4.3) at baseline to 1.1 (2.3) at Week 96[2]
- **Maintenance of response:** Among patients who responded to bimekizumab treatment at one year, the majority maintained response to two years.[1] Among Week 48 HiSCR50 and HiSCR75 responders, 90.0% (332/369) and 86.9% (265/305), respectively, maintained response through Week 96[1]
    - HiSCR50 and HiSCR75 are defined as at least either a 50 or 75% reduction from baseline in the total abscess and inflammatory nodule count, with no increase from baseline in abscess and inflammatory nodule or draining tunnel count[7]
    - Among Week 48 Dermatology Life Quality Index (DLQI) minimal clinically important difference (MCID) responders, 86.0% (234/272) maintained response through Week 96[1]
- **Symptom severity impact on health-related quality of life (HRQoL):** Data investigated the association between the severity of HS core symptoms beyond skin pain (itch, smell or odor and drainage or oozing) with HRQoL over 2 years.[3] Patients reporting no/mild symptom severity demonstrated greater improvements in HRQoL, as measured by HS Quality of Life (HiSQOL) patient-reported outcome questionnaire, compared with those reporting moderate and severe/very severe symptoms[3†]

[†]Observed case.

**About hidradenitis suppurativa**

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Hidradenitis suppurativa (HS) is a chronic, painful, and debilitating inflammatory skin disease that is associated with systemic manifestations.[6,11] 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.[6,11] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[6,11] HS develops in early adulthood and affects approximately one percent of the population in most studied countries.[6,11]

**^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).[7] The two studies had a combined enrolment of 1,014 participants.[7] 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 (Q2W/Q2W, BKZQ2W/Q4W, BKZQ4W/Q4W or placebo/BKZQ2W).[7]

Patients who completed Week 48 could enroll in the open-label extension.[10] 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; 446 patients in the open-label extension study completed Week 96.[10]

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

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

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

The approved indications for bimekizumab▼ in the European Union are:[9]

- **Plaque psoriasis:** Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy

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- **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, oedema, pain, swelling, haematoma), 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)

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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: January 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: February 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.*

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**Forward looking statements**

This press release may contain forward-looking statements including, without limitation, statements containing the words "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 guarantees of 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 differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: 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; 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, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, will progress to product approval 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 differences 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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## References

**1.** Porter ML, Chovatiya R, Gulliver W, et al. Bimekizumab 2-year Maintenance of Response in Week 48 responders in Moderate to Severe HS: Data from BE HEARD EXT [abstract]. EHSF 2025. #136.
**2.** Zouboulis CC, Goldfarb N, Molina-Leyva A, at al. Bimekizumab Impact on HS Disease Severity Measured by IHS4 and Draining Tunnel Count Over 2 Years: Data from BE HEARD EXT [abstract]. EHSF 2025. #189.
**3.** Ingram JR, Gottlieb AB, Thorlacius L, et al. Bimekizumab impact on the association between HS symptom severity beyond skin pain and health-related quality of life in BE HEARD EXT [abstract]. EHSF 2025. #49.
**4.** Tzellos T, van Straalen KR, Marzano AV, et al. Bimekizumab Impact on Dichotomous IHS4 Response Levels Over 2 Years: Results from BE HEARD EXT [abstract]. EHSF 2025. #130.
**5.** Naik HB, Daveluy S, Prens E, et al. Bimekizumab Impact on Flare in HS over 2 Years: Data from BE HEARD EXT [abstract]. EHSF 2025. #193.
**6.** Sabat R, Jemec GBE, Matusiak L, et al. Hidradenitis suppurativa. Nat Rev Dis Primers. 2020;6(1):18.
**7.** Kimball AB, Jemec GBE, Sayed CJ, et al. Efficacy and safety of bimekizumab in patients with moderate-to-severe hidradenitis suppurativa (BE HEARD I and BE HEARD II): two 48-week, randomised, double-blind, placebo-controlled, multicentre phase 3 trials. Lancet. 2024;403(10443):2504–19.
**8.** Zouboulis CC, Tzellos T, Kyrgidis A, et al. Br J Dermatol. 2017;177(5):1401–09.
**9.** BIMZELX® (bimekizumab) EU SmPC. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Accessed February 2025.
**10.** Zouboulis CC, Garg A, Sayed CJ, et al. Bimekizumab efficacy and safety through 2 years in patients with hidradenitis suppurativa: Results from the phase 3 BE HEARD I&II trials and open-label extension BE HEARD EXT. Abstract presented at EADV 2024. Amsterdam, Netherlands. September 2024.
**11.** Jemec GBE. Clinical practice. Hidradenitis suppurativa. N Engl J Med. 2012;366(2):158–64.
**12.** BIMZELX® (bimekizumab) U.S. PI. https://www.ucb-usa.com/Innovation/Products/BIMZELX. Accessed February 2025.

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