UCB News

BIMZELX[®]▼(bimekizumab) new three-year data in hidradenitis suppurativa at EADV showed sustained disease control across the most stringent clinical endpoints

- **Disease control sustained to three years:** Improvements in the stringent endpoints HiSCR75, HiSCR90 and HiSCR100 at one year were sustained and further improved to three years in 81.2%, 64.3% and 50.1% of patients, respectively*
- **Resolution of inflammatory lesions:** Of patients who achieved IHS4-100 at year one, 64.3% achieved and sustained this complete resolution of inflammatory lesions through to two years*
- **Impact of earlier treatment:** Across the high-efficacy IHS4 thresholds, patients treated earlier with bimekizumab had improved outcomes at two years*
- **Unique dual inhibition:** BIMZELX®▼(bimekizumab) is the first and only approved medicine designed to selectively inhibit interleukin 17A (IL-17A) and interleukin 17F (IL-17F)

Brussels (Belgium), September 17, 2025 – 07:05 (CEST) – UCB, a global biopharmaceutical company, today announced three-year data from the BE HEARD trials^ for BIMZELX® (bimekizumab) in moderate to severe hidradenitis suppurativa (HS). Bimekizumab, the first and only medicine approved to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F),[1] continues to be generally well tolerated, and demonstrated sustained disease control and durable resolution of key HS symptoms.[2,3,4,5,6,7,8]

"A crucial goal for treating people with hidradenitis suppurativa is achieving and maintaining long-term disease control at the most stringent levels," said John Ingram, Professor of Dermatology, Cardiff University. "These data for bimekizumab – including HiSCR100 and IHS4-100 – showed disease control can be maintained long-term. Importantly, the resolution of inflammatory lesions highlights the potential to prevent long-term structural damage commonly associated with this disease."

Among patients with HS, improvements in HiSCR50/75/90/100 seen at one year were sustained and further improved to three years in 90.2% (331/367), 81.2% (298/367), 64.3% (236/367) and 50.1%

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(184/367) of patients, respectively.[2]* Improvements in quality of life, as measured by DLQI 0/1, seen at year one in 27.4% (151/551) of patients were sustained to three years, with 38.1% (137/360) of patients reporting no effect of skin disease on their quality of life.[2]* Patients who achieved IHS4-55/75/90/100 at Week 48 sustained this response to two years in 90.8% (315/347), 85.1% (235/276), 71.2% (136/191) and 64.3% (74/115) of cases, respectively.[3]* Patients with shorter disease duration since HS diagnosis had better outcomes than those with longer disease duration, particularly at higher efficacy thresholds, emphasizing the potential impact of earlier treatment with bimekizumab upon diagnosis.[4]* At Week 96, proportions of patients in the lowest disease duration quartile (<2.38 years [n=115]) achieving IHS4-55/75/90/100 were 88.7% (n=102), 73.9% (n=85), 59.1% (n=68) and 46.1% (n=53), respectively.[4]* Similarly, IHS4-55/75/90/100 responses in the highest disease duration quartile (≥10.74 years [n=101]) at Week 96 were 77.2% (n=78), 62.4% (n=63), 39.6% (n=40) and 22.8% (n=23), respectively.[4]* Over two years, at the patient level, bimekizumab treatment reduced the number of draining tunnels in the majority of individuals.[5]* In addition, over two years of treatment with bimekizumab, a greater reduction in skin pain severity translated into an improvement in health-related quality of life for people living with HS.[6]*

"The three-year data on bimekizumab presented at EADV demonstrated deep and sustained responses across stringent efficacy endpoints, as well as long-term improvements in health-related quality of life – raising the treatment bar for people living with hidradenitis suppurativa," said Donatello Crocetta, Head of Medical and Chief Medical Officer, UCB. "Long-term efficacy and safety data are vital for advancing understanding of chronic inflammatory conditions like hidradenitis suppurativa, and these findings underscore UCB's commitment to advancing science-led insights and providing transformative treatment options to improve outcomes for patients."

Treatment with bimekizumab was generally well tolerated, with no new safety signals observed up to three years.[2]* The safety profile up to three years was consistent with years one and two.[2]* The most common TEAEs were hidradenitis (19.6/100 patient years [PY]), coronavirus infection (14.1/100 PY) and oral candidiasis (9.3/100 PY).[2]*

UCB's data on bimekizumab in hidradenitis suppurativa will be presented at the European Academy of Dermatology and Venereology (EADV) 2025 Congress in Paris, France, 17–20 September. The abstracts are part of the 19 presentations from UCB across bimekizumab in psoriasis, psoriatic arthritis, axial spondyloarthritis, as well as the abstract for the investigational therapy galvokimig in atopic dermatitis.[†]

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*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. 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]

Receiving BKZ Q2W to Week 16, then Q4W thereafter is the approved dosing regimen (Q2W/Q4W). 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 dose of BKZ across BE HEARD I & II and BE HEARD EXT (total of three years).

†Galvokimig is currently under clinical investigation, and is not approved by any regulatory authority worldwide.

Notes to Editors:

- 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
- IHS4-55/75/90/100: IHS4 is the clinician-rated International HS Severity Score System (IHS4), which evaluates the number of inflammatory nodules/abscesses/draining tunnels. IHS4-55/75/90/100 is defined as at least a 55%/75%/90%/100% improvement from baseline in a patient's IHS4 total score. IHS4-100 equates to complete resolution of inflammatory lesions[4]
- Draining tunnels: These are painful, pus-discharging tunnels under the skin resulting from long-term inflammation, frequently leading to scarring[9]
- DLQI 0/1: Dermatology Life Quality Index (DLQI) is a patient-reported questionnaire consisting of 10 questions concerning symptoms and feelings, daily activities, leisure, work, and school, personal relationships and treatment.[10] Each question is scored from 0 to 3 and the scores summed, giving a range from 0 (no impairment of life quality) to 30 (maximum impairment).[10] All questions relate "to the last week". The DLQI was designed to be used in adults over the age of 18 years.[10] DLQI 0/1 denotes the percentage of patients who achieved an overall score of 0 or 1 in the questionnaire, and denotes no effect at all on a patient's quality of life.[10]

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About hidradenitis suppurativa

Hidradenitis suppurativa (HS) is a chronic, painful and potentially debilitating inflammatory skin disease that is associated with systemic manifestations.[11,12] 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.[11,12] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[11,12] HS develops in early adulthood and affects approximately one percent of the population in most studied countries.[11,12]

^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).[13] The two studies had a combined enrollment of 1,014 participants.[13] 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, BKZQ2W/Q4W, BKZQ4W/Q4W or placebo/BKZQ2W).[13]

Patients who completed Week 48 could enroll in the open-label extension.[14] 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,[11] and 367 completed Week 148.[2]

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.[1]

About BIMZELX® ▼ (bimekizumab) EU/EEA§

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

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- **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.

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

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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 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

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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.

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