UCB News

UCB announces late-breaking two-year data for BIMZELX® ▼(bimekizumab) in moderate to severe hidradenitis suppurativa at EADV 2024

- Clinically meaningful improvements observed with bimekizumab over one year of treatment were maintained up to two years (Week 96)
- At Week 96, over eight in 10 patients treated with bimekizumab achieved HiSCR50, over seven in 10 achieved HiSCR75, and over four in 10 achieved HiSCR100
- Approximately one in three patients treated with bimekizumab reported minimal or no impact of the disease on their health-related quality of life over two years

Brussels (Belgium), September 27, 2024 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced the first presentation of two-year data from the Phase 3 studies, BE HEARD I and BE HEARD II, and their open-label extension, evaluating the efficacy and safety of bimekizumab, an IL-17A and IL-17F inhibitor, in adults with moderate to severe hidradenitis suppurativa (HS).[1] These new data are presented today as a late-breaking platform presentation at the 33rd European Academy of Dermatology and Venereology (EADV) Congress in Amsterdam, the Netherlands, 25–28 September 2024.

Results showed that the clinically meaningful improvements observed with bimekizumab treatment at one year were maintained over two years.[1*] At Week 96, 85.4 percent (n=381/446) of patients treated with bimekizumab achieved HS Clinical Response 50 (HiSCR50). The more stringent endpoints, HiSCR75 and HiSCR100, were achieved by 77.1 percent (n=344/446) and 44.2 percent (n=197/446) of patients, respectively.[1*] Improvements in the severity of disease, reductions in draining tunnel count and improvements in health-related quality of life were also maintained over two years.[1*] Bimekizumab was generally well tolerated and no new safety signals were observed.[1]

"Hidradenitis suppurativa is a chronic, relapsing and painful inflammatory skin disease that significantly impacts patients' quality of life. The bimekizumab data presented at EADV 2024 showed maintained improvements in clinical response, symptoms, severity and quality of life over two years. These findings are particularly encouraging given the need for new treatment options that offer sustained relief for patients," said Professor Christos C. Zouboulis, President of the European

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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.

"In moderate to severe hidradenitis suppurativa, healthcare professionals and patients value long-term data when they are making treatment decisions. We are proud to present, for the first time, the bimekizumab two-year results at EADV 2024," said Fiona du Monceau, Executive Vice President, Head of Patient Evidence, UCB. "These longer-term data build on the 48-week results, demonstrating maintained response over two years, which is highly relevant for the hidradenitis suppurativa community."

Summary of the bimekizumab two-year data in moderate to severe HS presented at EADV 2024:

Patients who completed Week 48 in BE HEARD I and BE HEARD II could enroll in the open-label extension study and received bimekizumab every two weeks (Q2W) or every four weeks (Q4W) based on ≥90 percent HiSCR averaged from Weeks 36, 40 and 44. Results are shared for the bimekizumab total patient group.

- *HS Clinical Response:*
  - HiSCR50 was achieved by 79.9 percent (n=444/556) of bimekizumab patients at Week 48 and 85.4 percent (n=381/446) at Week 96.[1*]
  - HiSCR75 was achieved by 64.0 percent (n=356/556) of bimekizumab patients at Week 48 and 77.1 percent (n=344/446) at Week 96.[1*]
  - HiSCR90 was achieved by 42.3 percent (n=235/556) of bimekizumab patients at Week 48 and 57.6 percent (n=257/446) at Week 96.[1*]
  - HiSCR100 was achieved by 30.2 percent (n=168/556) of bimekizumab patients at Week 48 and 44.2 percent (n=197/446) at Week 96.[1*]

- *International HS Severity Score System (IHS4)*: Patients treated with bimekizumab saw a decrease in the severity of their HS symptoms as measured by the IHS4 score.[1*] The mean IHS4 score at baseline was 35.6±31.5 among bimekizumab patients.[1*] The percent change from baseline in IHS4 score at Week 48 among bimekizumab patients was maintained through Week 96 (-70.3±39.6 and -79.8±28.1 at Week 48 and Week 96, respectively).[1*]

- *Draining tunnel (DT) count*: The mean DTs at baseline was 3.8±4.3 among bimekizumab patients.[1*] The percent change from baseline in draining tunnel count at Week 48 among bimekizumab patients was maintained through Week 96 (–57.5 ±72.9 and –73.7±45.7 percent at Week 48 and Week 96, respectively).[1*]

GL-BK-2400102
Date of preparation: September 2024

- *Health-related quality of life*: The proportion of bimekizumab patients who achieved Dermatology Life Quality Index (DLQI) 0/1 at Week 48 was maintained through Week 96. The Mean DLQI Total at baseline was 11.0±6.8 among bimekizumab patients. Approximately one in three patients reported minimal or no impact of the disease on their health-related quality of life over two years (27.4 percent [n=151/155] and 33.9 percent [n=149/439] at Week 48 and Week 96, respectively).[1*]

Bimekizumab was generally well-tolerated over two years with no new safety signals observed. Over two years, 917/995 patients who received ≥1 dose of bimekizumab experienced a treatment-emergent adverse event (TEAE). Serious TEAEs were reported in 122 patients.[1] Over two years, the most common TEAEs (exposure adjusted incidence rates) were hidradenitis (20.5), coronavirus infection (15.3) and oral candidiasis (10.5).[1]

Notes to Editors:
* Observed Case

About hidradenitis suppurativa

Hidradenitis suppurativa (HS) is a chronic, painful, and debilitating inflammatory skin disease that is associated with systemic manifestations.[2,3] 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.[2,3] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[2,3] HS develops in early adulthood and affects approximately one percent of the population in most studied countries.[2,3]

About BE HEARD I/BE HEARD II and the Open-Label Extension Study

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).[4] The two studies had a combined enrolment of 1,014 participants.[4] In each study, patients were randomized 2:2:2:1 (initial [16-week]/maintenance [32-weeks]) to bimekizumab 320 mg every two weeks, four weeks or a combination (Q2W/Q2W, Q2W/Q4W, Q4W/Q4W or placebo/Q2W).[1] Patients who completed Week 48 could enroll in the open-label extension.[1] 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.[1] The primary endpoint in both trials was HiSCR50 at Week 16.[4] A key secondary endpoint was HiSCR75 at Week 16.[4] HiSCR50 and HiSCR75 are defined as at least either a 50 or 75 percent reduction from baseline

GL-BK-2400102
Date of preparation: September 2024

in the total abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count.[4]

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

The approved indications for bimekizumab▼ in the EU are:[5]

- 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 percent, 14.6 percent, 16.3 percent, 8.8 percent in plaque psoriasis, psoriatic arthritis, axial spondyloarthritis (axSpA) and hidradenitis suppurativa, respectively) and oral candidiasis (7.3 percent, 2.3 percent, 3.7 percent, 5.6 percent 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, fatigue. Elderly may be more likely to experience certain adverse reactions such as oral candidiasis, dermatitis and eczema when using bimekizumab.

GL-BK-2400102
Date of preparation: September 2024

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: August 2024. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

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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

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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.

GL-BK-2400102
Date of preparation: September 2024

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GL-BK-2400102
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