UCB News

Bimekizumab 48-week Phase 3 analyses in moderate to severe hidradenitis suppurativa showed sustained improvements in skin pain and draining tunnel count

- Patients treated with bimekizumab demonstrated clinically meaningful improvements in skin pain up to 48 weeks, across various assessed outcomes
- At Week 16, patients treated with bimekizumab demonstrated greater draining tunnel reductions versus placebo that were sustained or improved to Week 48
- Disease-associated pain and draining tunnels can highly impact the quality of life of people living with moderate to severe hidradenitis suppurativa

Brussels (Belgium), 8 March, 2024 – 18:00 (CET) – UCB, a global biopharmaceutical company, today announced 48-week post-hoc analyses of pooled Phase 3 data from the BE HEARD I and BE HEARD II studies examining the impact of bimekizumab on skin pain and draining tunnels in adults with moderate to severe hidradenitis suppurativa (HS). These results are shared at the 2024 American Academy of Dermatology (AAD) Annual Meeting in San Diego, California, U.S., March 8–12.

Analyses showed that bimekizumab-treated patients reported clinically meaningful improvements in skin pain up to 48 weeks across various assessed outcomes, including the HS Symptom Questionnaire (HSSQ) skin pain item, the Patient Global Impression of Severity of Skin Pain (PGI-S-SP) and the Change in Severity of Skin Pain (PGI-C-SP).[1] Additionally, patients demonstrated greater reductions in draining tunnel count compared to those on placebo at Week 16. Responses were either sustained or improved to Week 48.[2]

"The majority of patients with hidradenitis suppurativa experience disease-associated pain that can impact their quality-of-life. Data from the Phase 3 studies show that after 48 weeks of bimekizumab treatment approximately six out of ten patients rated their skin pain 'much better'," said Dr. Hadar Lev-Tov, MD, Associate Professor, Dr. Phillip Frost Department of Dermatology and Cutaneous Surgery, University of Miami, Miller School of Medicine, Florida, U.S. "These long-term results are encouraging, especially given that pain is a common complaint in people with HS that dermatologists struggle with daily."

"The bimekizumab 48-week long-term data in moderate to severe hidradenitis suppurativa showed sustained improvements in skin pain and draining tunnel count. These positive results underscore our commitment to developing solutions that make a meaningful and lasting difference to peoples' lives," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. "We are actively pursuing regulatory applications across the globe to bring bimekizumab to the hidradenitis suppurativa community."

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Bimekizumab is not approved for the treatment of moderate to severe HS by any regulatory authority worldwide. The efficacy and safety profile of bimekizumab in the treatment of moderate to severe HS have not been established and this is an investigational indication only.

At baseline, adult patients (N=1,014) were randomized 2:2:2:1 (initial/maintenance) to receive, either bimekizumab 320 mg every two weeks Q2W/Q2W (n=288), bimekizumab Q2W/Q4W (n=292), bimekizumab Q4W/Q4W (n=288) or placebo/bimekizumab Q2W (n=146).[1,2] Across treatment groups, the mean baseline HSSQ skin pain score was 5.8 (on a scale of 0-10, with higher score indicating more pain).[1] At baseline, 72.8 percent of patients had draining tunnels with the count comparable across regimens (mean range 3.3–3.8).[2]

Highlights of the bimekizumab data in moderate to severe HS presented at AAD 2024:

Impact on pain:

- At Week 48, HSSQ skin pain response was achieved by 64.6–75.7 percent of patients.[1*]
- At Week 48, HSSQ skin pain score of 0 was achieved by 12.7–19.8 percent of patients.[1*]
- From Weeks 0–48, HSSQ skin pain scores reduced by 36.9–43.7 percent across treatment groups.[1±]
- At Week 48, 55.9–63.7 percent of patients rated their skin pain "much better" using the PGI-C-SP.[1*]
- At Week 48, 3.9–7.8 percent rated PGI-S-SP "severe" vs. 28.5-33.3 percent at baseline and 45.6–47.4 rated PGI-S-SP "mild" vs. 15.1–16.7 percent at baseline.[1*]

Impact on draining tunnel count:

- At Week 16, the draining tunnel percent change from baseline (CfB) was higher with bimekizumab vs. placebo (-43.9 to -45.7 vs. -21.5 percent). Bimekizumab-treated patients also saw greater absolute changes in draining tunnel count vs. placebo.[2±]
- The percentage and absolute CfB increased through Week 48 across all bimekizumab groups.[2±]
- At Week 16, greater proportions of bimekizumab-treated patients saw draining tunnel reductions of three or more vs. those on placebo (58.0–70.6 vs. 35.0 percent), with responses sustained or improved to Week 48 across regimens (79.4–88.7 percent).[2*]

*Observed case. ±Multiple imputation

Notes to editors:

About hidradenitis suppurativa (HS)

Hidradenitis suppurativa (HS) is a chronic, recurring, painful, and debilitating inflammatory skin disease.[3,4] 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.[3,4] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[3,4] HS develops in early adulthood and affects approximately one percent of the population in most studied countries.[3,4]

About BE HEARD I and BE HEARD II

The efficacy and safety profile of bimekizumab were evaluated in adult patients with moderate to severe hidradenitis suppurativa (HS) in two multicentre, randomized, double-blind, placebo-controlled Phase 3 studies (BE HEARD I and BE HEARD II).[5,6] The two studies had a combined enrolment of 1,014 participants.[5,6] The primary endpoint in both trials was HiSCR50 at Week 16.[5,6] A key secondary endpoint was HiSCR75 at Week 16.[5,6] HiSCR50 and HiSCR75 are defined as at least either a 50 or 75 percent reduction from baseline in the

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total abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count.[5,6]

About BIMZELX®

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.[7]

In the U.S., bimekizumab-bkzx is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[8]

Bimekizumab is not approved in the U.S. for the treatment of moderate to severe hidradenitis suppurativa (HS). The efficacy and safety profile of bimekizumab in HS have not been established, and it is not approved for use in HS by any regulatory authority worldwide.

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. [9]
- **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). [9]
- **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.[9]

The label information may differ in other countries where approved. Please check local prescribing information.

In the U.S., bimekizumab-bkzx is not approved for the treatment of psoriatic arthritis or axial spondyloarthritis and these are investigational indications only.

BIMZELX U.S. IMPORTANT SAFETY INFORMATION[8]

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

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 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, advise to promptly seek medical attention, refer to a mental health professional as appropriate, and re- evaluate the risks and benefits of continuing treatment.

Infections

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BIMZELX may increase the risk of 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

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 adverse reactions (≥ 1%) are upper respiratory infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes Simplex Infections, acne, folliculitis, other Candida infections, and fatigue.

BIMZELX®▼(bimekizumab) EU/EEA* Important Safety Information[9]

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%, 14.6%, 16.3% in plaque psoriasis (PSO), psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA), respectively) and oral candidiasis (7.3%, 2.3%, 3.7% in PSO, PsA and axSpA, respectively). Common adverse reactions (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, headache, rash, dermatitis and eczema, acne, injection site reactions, fatigue. Elderly may be more likely to experience certain adverse reactions such as oral

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candidiasis, dermatitis and eczema when using bimekizumab.

Bimekizumab is contraindicated in patients with hypersensitivity to the active substance or 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: November 2023.

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 2024.

▼*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.

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