UCB News

Latest analyses of bimekizumab phase 3 studies in moderate to severe hidradenitis suppurativa to be presented at EHSF 2024

- At Week 48, ~7 of 10 patients treated with bimekizumab achieved IHS4-55, an IHS4 dichotomous outcome, that measures treatment effect and signifies reduction in abscesses, nodules and draining tunnels
- Bimekizumab treatment demonstrated improvements in overall lesion count and lesion clearance, across abscesses, inflammatory nodules and draining tunnels over 48 weeks
- Patient-reported data showed that high levels of clinical responses observed with bimekizumab treatment translated into benefits in health-related quality of life

Brussels (Belgium), 9th February 2024 – 07:00 CET – UCB, a global biopharmaceutical company, today announced results from the latest post hoc analyses of the Phase 3 studies, BE HEARD I and BE HEARD II, evaluating the efficacy and safety of bimekizumab in the treatment of adults with moderate to severe hidradenitis suppurativa (HS).[1,2,3,4] These data are being presented at the 13th Conference of the European Hidradenitis Suppurativa Foundation (EHSF) in Lyon, France (7-9 February).

"The analyses presented at EHSF 2024 build on the Phase 3 data communicated to date and reinforce our belief in the potential of bimekizumab to make a meaningful difference to patients," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions, and Head of U.S., UCB. "Results presented re-affirm the high levels of sustained clinical response achieved with bimekizumab treatment, the positive impact on health-related quality of life as reported by patients, and the importance of timely treatment following diagnosis."

"The achievement of IHS4-55 shows reduction in inflammatory nodules, abscesses and draining tunnels. This is a novel dichotomous version of the International Hidradenitis Suppurativa Severity Score System that allows for the inclusion and quantification of draining tunnels in a validated manner and reflects at least 55% improvement in the total score from baseline. With bimekizumab, the analyses showed that over 48 weeks, the majority of patients, ~7 out of 10, achieved IHS4-55," said Professor Tzellos, Department of Dermatology, Nordland Hospital Trust, Bodø, Norway.

The efficacy and safety of bimekizumab in HS have not been established and it is not approved for use in HS by any regulatory authority worldwide.

The BE HEARD I and II studies included an initial (Weeks 0–16) and maintenance treatment period (Weeks 16–48). 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). Primary data from these studies have been previously reported.[1,2,3]

Highlights of the bimekizumab BE HEARD I and BE HEARD II Data Presented at EHSF 2024

- **Dichotomous IHS4:** At Week 16, a greater proportion of patients achieved IHS4-55 with bimekizumab treatment vs placebo (51.1-62.9% vs. 25.7–30.8%).[1†] By Week 48, these responses were sustained or increased (pooled, 71.0–77.4%).[1†] Patients that switched from placebo to bimekizumab achieved

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comparable responses to those receiving continuous bimekizumab treatment (pooled, 76.2%).[1†] The higher thresholds of IHS4-75 and IHS4-90 were also achieved by greater proportions of patients treated with bimekizumab vs placebo at Week 16 (IHS4-75: 30.6–44.7% vs 15.7–23.1%; IHS4-90: 16.5–23.0% vs 7.1–10.8%).[1†] By Week 48, these responses were sustained or increased (IHS4-75 pooled, 56.0-61.9%; IHS4-90 pooled, 36.2-44.1%).[1†]

- **Lesion Count and Clearance Across Lesion Type and Anatomical Area:** At Week 16, bimekizumab treatment demonstrated improvements in overall lesion count. Following bimekizumab treatment lesion clearance also increased at Week 16.[2] Results were sustained or improved across 48 weeks of treatment.[2] Improvements were observed across different anatomical regions and across all three lesion types presented (abscesses, inflammatory nodules and draining tunnels).[2]
- **Depth of Response and Impact on Quality of Life:** The vast majority of patients (69.5–74.8%) who achieved Hidradenitis Suppurativa Clinical Response 50 (HiSCR50) at Week 16 reported a Hidradenitis Suppurativa Quality of Life (HiSQoL) rating of 'None/Mild' at Week 16.[3] A higher proportion of patients reported a HiSQoL rating of 'None/Mild' at Week 16 if they achieved HiSCR75 (77.2–84.3%) or HiSCR90 (80.0–89.3%) at Week 16.[3] A similar trend was also observed at Week 48.[3]
- **Clinical Response Across Duration Quartiles:** At Week 16, patients treated with bimekizumab in the lowest (<2.40 years) disease duration quartiles achieved HiSCR50/HiSCR75 of 67.5% (n=133/197)/48.2% (95/197) vs 43.8% (n=14/32)/21.9%(n=7/32) for placebo.[4] Patients treated with bimekizumab in the highest (≥10.87 years) disease duration quartiles achieved HiSCR50/HiSCR75 of 53.8% (n=99/184)/34.2% (n=63/184) vs. 28.9% (n=13/45)/20.0% (n=9/45) for placebo. Results with bimekizumab were sustained across 48 weeks of treatment.[4]

[†]Observed Case Analysis

Notes to editors:

About BE HEARD I and BE HEARD II

BE HEARD I and BE HEARD II are randomized, double-blind, placebo-controlled, parallel-group, multicenter, Phase 3 studies designed to evaluate the efficacy and safety of bimekizumab in adults with moderate to severe hidradenitis suppurativa (HS).[1,2,3,4] The primary endpoint in both studies was HiSCR50 at Week 16.[5] A key secondary endpoint was HiSCR75 at Week 16. 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 or draining tunnel count.[5]

About IHS4-55, IHS4-75 and IHS4-90

Hidradenitis suppurativa (HS) severity can be assessed using the International Hidradenitis Suppurativa Severity Score System (IHS4) that includes the number of inflammatory nodules, abscesses and draining tunnels and classifies disease severity as mild (≤3 points), moderate (4–10 points) or severe (≥11 points).[1] In order to discriminate between active treatment and placebo, a novel outcome measure built on the IHS4 was developed using dichotomous thresholds.[1] IHS4-55 is a dichotomous version of IHS4 that is based on an improvement of at least 55% in the total score from baseline.[1] IHS4-55 response is achieved if a patient's IHS4 score improves by at least 55% from baseline.[1] Similarly, IHS4-75 and IHS4-90 responses are achieved if a patient's IHS4 score improves by 75% or 90%, respectively, from baseline.[1]

About hidradenitis suppurativa (HS)

Hidradenitis suppurativa (HS) is a chronic, recurring, painful, and debilitating inflammatory skin disease that is

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associated with systemic manifestations.[6,7] The main symptoms are nodules, abscesses, and pus-discharging fistulas (channels leading out of the skin) which typically occur in the armpits, groin, and buttocks.[6,7] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life. HS most commonly develops in early adulthood and affects approximately one percent of the population in most studied countries.[6,7] Approximately one-third of people with HS have a family history of HS, and lifestyle factors such as smoking and obesity can also play a crucial role in the clinical course of HS.[8] The symptoms of pain, discharge and scarring are not only a physical burden.[6,7] People with HS also experience stigma: worrying about, or directly experiencing, negative attitudes and reactions from society in response to their symptoms.[6,7,9] These feelings can lead to embarrassment, social isolation, low self-esteem and sexual life impairment, and impact all areas of life, including interpersonal relationships, education, and work.[9]

About BIMZELX® ▼ [10]

BIMZELX® (bimekizumab) 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.[11] The therapeutic indications in the European Union are:

- **Plaque psoriasis:** Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[10]
- **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).[10]
- **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.[10]

BIMZELX® (bimekizumab) EU/EEA* Important Safety Information[10]

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 and fatigue. Elderly individuals 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 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.

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

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*EU/EEA means European Union/European Economic Area

▼ *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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