UCB News

Phase 3 Data Analysis Presented at EADV 2023 Showed Bimekizumab Achieved High Thresholds of Clinical Response in Hidradenitis Suppurativa

- Bimekizumab treatment resulted in clinically meaningful improvements in HiSCR50 and the more stringent endpoints HiSCR75, HiSCR90 and HiSCR100 vs. placebo at Week 16, with improvements increasing for patients remaining in the study through Week 48
- Over 8 in 10 patients treated with bimekizumab who achieved a HiSCR50 response after 16 weeks, maintained response to Week 48

Brussels (Belgium), October 12 2023 – 18:00 (CEST) – UCB, a global biopharmaceutical company, today announced the first analyses of pooled data from the two Phase 3 bimekizumab studies (BE HEARD I and BE HEARD II) in moderate to severe hidradenitis suppurativa (HS).[1,2,3,4] These analyses are among bimekizumab data in HS presented this week across three oral presentations and several posters at the 2023 European Academy of Dermatology and Venereology (EADV) Congress in Berlin, Germany, October 11–14.

"Patients with hidradenitis suppurativa live with one of the most burdensome chronic systemic skin diseases. There is a compelling need for new treatment options that can offer high and durable clinical response," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. "Data presented at EADV showed that over 48 weeks many patients treated with bimekizumab achieved high thresholds of response. These findings suggest that inhibition of IL-17F in addition to IL-17A represents a promising treatment approach in moderate to severe hidradenitis suppurativa."

"The bimekizumab Phase 3 clinical trial program in hidradenitis suppurativa included the more stringent clinical outcomes of HiSCR75, HiSCR90 and HiSCR100 in addition to the standard HiSCR50. In these studies, bimekizumab demonstrated clinical meaningful improvements for these outcomes over placebo at Week 16, with improvements increasing for patients remaining in the studies through Week 48. In addition, improvements in disease severity were seen over time, with the majority of patients with severe hidradenitis suppurativa at baseline shifting to mild to moderate disease according to the IHS4 dynamic classification system," said Professor Christos C. Zouboulis, President of the European Hidradenitis Suppurativa Foundation, 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.

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

Data were pooled from the BE HEARD I and II studies, which included an initial (Weeks 0–16) and maintenance treatment period (Weeks 16–48).[1,2,3,4] 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/every four weeks (Q4W); n=292; bimekizumab Q4W/Q4W (n=288) or placebo/bimekizumab Q2W (n=146).[1,2,3,4]

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Highlights from the pooled data analysis (BE HEARD I and BE HEARD II)

- Bimekizumab-treated patients showed higher response rates in the primary endpoint (HiSCR50) at Week 16 vs. placebo (58 percent Q2W/Q2W, 55.9 percent Q2W/Q4W, 56.1 percent Q4W/Q4W vs. 33.4 percent for placebo).[†1] Improvements increased for patients through Week 48 with almost 8 in 10 achieving HiSCR50.[‡1] At Week 48, the response in patients who switched from placebo to bimekizumab at Week 16 approached that reached by patients on bimekizumab from baseline (70.5 percent [n=74/105]).[‡1]

- A similar trend was seen in the more stringent HiSCR75 and HiSCR90 endpoints through Week 48.[‡1,5,6] Bimekizumab-treated patients had improved responses at Week 48 with approximately 6 in 10 patients achieving HiSCR75.[‡1] Analysis of the most stringent endpoint, HiSCR100, showed numerically higher responses in bimekizumab patients vs. placebo at Week 16, and improved responses at Week 48 with approximately 3 out of 10 patients achieving HiSCR100. Patients who switched from placebo to bimekizumab at Week 16 demonstrated a similar trend in HiSCR100 rates at Week 48.[‡1]

- Across all bimekizumab treatment groups, over 8 out of 10 patients who achieved HiSCR50 at Week 16 (n=160 Q2W/Q2W; n=155 Q2W/Q4W; n=152 Q4W/Q4W), maintained the response through Week 48.[‡2] In addition, across all bimekizumab treatment groups, more than 8 out of 10 patients who achieved an abscess and inflammatory nodule (AN) count of 0,1 or 2 at Week 16 (n=104 Q2W/Q2W, n=99 Q2W/Q4W; n=87 Q4W/Q4W) maintained this response to Week 48.[‡2]

- According to the International Hidradenitis Suppurativa Severity Score System (IHS4), at baseline, 83.7–88.4 percent of the enrolled patients across bimekizumab dosing regimens had severe HS.[3] A post hoc analysis showed that at Week 16 higher proportions of bimekizumab-treated patients had mild HS vs. placebo (24.6–27.2 percent vs. 15.3 percent).[3] Similar trends were observed for patients with moderate HS (25.8–28.0 percent vs. 17.1 percent).[3] Improvements in IHS4 categories were sustained over time across bimekizumab groups. At Week 48, 37.3–40.1 percent had mild HS and 23.8–25.3 percent had moderate HS.[3]

- Analyses showed that regardless of weight and body mass index category, a higher proportion of patients treated with bimekizumab vs. placebo achieved clinical response at Week 16 (HiSCR50, HiSCR75 and HiSCR90) with increasing levels of response between Week 16 and Week 48.[4]

- The safety profile of bimekizumab across BE HEARD I and BE HEARD II was consistent with previous studies with no new safety signals observed.[1] The most frequently reported TEAEs in 995 patients receiving ≥1 dose of bimekizumab were hidradenitis (18.7 percent), oral candidiasis (11.2 percent), and coronavirus infection (10.8 percent).[1] Serious treatment emergent adverse events were reported in 7.0 percent Q4W/Q4W, 4.5 percent Q2W/Q4W and 8.1 percent Q2W/Q2W patients.[1]

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Notes to editors:

†Modified non-responder imputation
‡Observed Case

About Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa (HS) is a chronic, recurring, painful, and debilitating inflammatory skin disease, that is associated with systemic manifestations.[7,8] 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.[7,8] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[7.8] HS most commonly develops in early adulthood and affects approximately one percent of the population in most studied countries.[7,8] 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.[7,8] The symptoms of pain, discharge and scarring are not only a physical burden. People with HS also experience stigma: worrying about, or directly experiencing, negative attitudes and reactions from society in response to their symptoms.[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.[10]

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).[5,6] The two studies had a combined enrolment of 1,014 participants with a diagnosis of moderate to severe HS.[5,6] The primary endpoint in both studies 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 total abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count.[5,6]

About bimekizumab

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.[12]
- **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).[12]
- **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.[12]

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% 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

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

European SmPC date of revision: June 2023.
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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.*

For further information, contact UCB:

Investor Relations
Antje Witte
T: +32.2.559.94.14
email antje.witte@ucb.com

Corporate Communications
Laurent Schots
T: +32.2.559.92.64
email laurent.schots@ucb.com

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Brand Communications
Eimear O'Brien
T: +32.2.559.92.71
email eimear.obrien@ucb.com

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