UCB News

Bimekizumab Phase 3 Data in Hidradenitis Suppurativa Show Clinically Meaningful, Deep and Maintained Response over 48 Weeks

- Patients treated with investigational bimekizumab, an IL-17A and IL-17F inhibitor, achieved statistically significant and clinically meaningful improvements over placebo in signs and symptoms of hidradenitis suppurativa at week 16, as measured by HiSCR50
- Bimekizumab demonstrated deep levels of clinical response over placebo at week 16, as measured by HiSCR75, a key secondary endpoint
- Patients treated with bimekizumab experienced improved health-related quality of life over placebo at week 16, a key secondary endpoint
- Clinical responses were maintained with continuous bimekizumab treatment – over 75 percent of patients achieved HiSCR50, and over 55 percent achieved HiSCR75, at week 48±

Brussels (Belgium) 18th March 2023 – 19:10 (CET) – UCB, a global biopharmaceutical company, today announced detailed positive results from two 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] Data from the two studies showed that bimekizumab achieved statistically significant and consistent clinically meaningful improvements over placebo in the signs and symptoms of HS at week 16, which were maintained to week 48.[1,±] Clinical responses with bimekizumab were observed from the first dose with some patients achieving HiSCR50 at week four.[1] These new data were presented today at a late-breaking platform presentation at the 2023 American Academy of Dermatology (AAD) Annual Meeting in New Orleans, U.S., 17th-22nd March.

"Hidradenitis Suppurativa is a chronic, debilitating inflammatory skin disease for which only one approved treatment is available today," said Lead Investigator, Alexa B. Kimball, MD, MPH, Beth Israel Deaconess Medical Center and Professor of Dermatology, Harvard Medical School, Boston, MA, U.S. "Treating moderate to severe cases with bimekizumab has shown promising results in phase 3 patient trials, with sustained improvement after one year."

The two studies (n=505 in BE HEARD I; n=509 in BE HEARD II) evaluated two dose regimens of bimekizumab (320 mg every two weeks [Q2W] and 320 mg every four weeks [Q4W]) versus placebo over the 16-week initial and the 32-week maintenance treatment periods.[1] Data presented at AAD 2023 show that:

- A significantly higher proportion of patients treated with bimekizumab (Q2W) achieved HiSCR50, the primary endpoint, at week 16 vs. placebo in BE HEARD I and BE HEARD II (47.8 percent vs. 28.7 percent [p=0.006] and 52.0 percent vs. 32.2 percent [p=0.003], respectively).[1]

- A greater proportion of patients treated with bimekizumab (Q4W) achieved HiSCR50 at week 16 than placebo in BE HEARD I and BE HEARD II, with statistical significance achieved in BE HEARD II (45.3 percent vs. 28.7 percent [p=0.030] and 53.8 percent vs. 32.2 percent [p=0.004], respectively).[1]

- Patients treated with bimekizumab achieved deep levels of clinical response with a greater proportion achieving HiSCR75, a key secondary endpoint, at week 16 than placebo, with statistical significance in BE HEARD II with both dose regimens and for Q2W in BE HEARD I.[1]

- Patients treated with bimekizumab experienced improved health-related quality of life (change from baseline in the dermatology life quality index) compared with placebo at week 16 (BE HEARD I and BE HEARD II, Q2W and Q4W).[1]

- Clinical responses (HiSCR50 and HiSCR75) were maintained with continuous bimekizumab treatment – over 75 percent of patients achieved HiSCR50, and over 55 percent achieved HiSCR75 at week 48 (observed case analysis; BE HEARD I and BE HEARD II, Q2W and Q4W).[1]

"Today, at the largest dermatology meeting of the year, we unveiled 48-week data from our Phase 3 bimekizumab program in hidradenitis suppurativa. Results from the Phase 3 program highlight the meaningful clinical outcomes achieved by targeting IL-17F in addition to IL-17A," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. "We are now focused on the next steps with global regulatory filings for bimekizumab in hidradenitis suppurativa planned for later this year."

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 common (frequency of >5 percent) treatment emergent adverse events on bimekizumab over 16 weeks were hidradenitis (7.2 percent in BE HEARD I and 8.8 percent in BE HEARD II), oral candidiasis (4.4 percent in BE HEARD I and 6.7 percent in BE HEARD II), headache (7.0 percent in BE HEARD I and 5.8 in BE HEARD II) and diarrhea (7.0 percent in BE HEARD I and 5.3 percent in BE HEARD II).[1]

UCB expects to submit global regulatory applications for bimekizumab in moderate to severe HS starting in Q3 2023.

In the U.S., the efficacy and safety of bimekizumab have not been established for any indication and it is not approved by the U.S. Food and Drug Administration. In the European Union and Great Britain, bimekizumab is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[2,3] UCB is investigating bimekizumab in HS. The efficacy and safety of bimekizumab in HS have not been established, and it is not approved for use in this indication by any regulatory authority worldwide.

Notes to editors:

± Observed case analysis.

About BE HEARD I and BE HEARD II

BE HEARD I is a randomized, double-blind, placebo-controlled, parallel group, multicenter, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in adults with moderate to severe hidradenitis suppurativa (HS). BE HEARD I enrolled 505 participants with a diagnosis of moderate to severe HS. [1]

BE HEARD II is a randomized, double-blind, placebo-controlled, parallel group, multicenter, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in adults with moderate to severe HS. BE HEARD II enrolled 509 participants with a diagnosis of moderate to severe HS.[1]

BE HEARD I and II comprised double-blind 16-week initial and 32-week maintenance treatment periods. Participants with moderate to severe HS were randomized 2:2:2:1 to (initial/maintenance) bimekizumab 320mg every 2 weeks (Q2W)/Q2W, bimekizumab Q2W/Q4W, bimekizumab Q4W/Q4W, placebo/bimekizumab Q2W. Until week 16, bimekizumab Q2W/Q2W and bimekizumab Q2W/Q4W were combined to bimekizumab Q2W.[1]

The primary endpoint in both studies was HiSCR50 at week 16.[1] A key secondary endpoint was HiSCR75 at week 16.[1] 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.[4,5]

For additional details on the study, visit BE HEARD I on clinicaltrials.gov. For additional details on the study, visit BE HEARD II on clinicaltrials.gov.[4,5]

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) is a chronic, recurring, painful, and debilitating inflammatory skin disease.[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.[6,7]

HS develops in early adulthood, 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. 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.[6,8]

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.[2,10] In August 2021, bimekizumab was first approved in the European Union (EU)/European Economic Area (EEA) and in Great Britain, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[2,3] The label information may differ in other countries where approved. Please check local prescribing information. In the U.S., the efficacy and safety of bimekizumab have not been established for any indication and it is not approved by the U.S. Food and Drug Administration (FDA).

About BIMZELX® ▼ (bimekizumab) in the EU/EEA

In the EU/EEA, BIMZELX® is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[2]

BIMZELX® ▼ (bimekizumab) EU/EEA Important Safety Information in Psoriasis

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%) (most frequently nasopharyngitis) and oral candidiasis (7.3%). Common adverse reactions (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, headache, 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 administered 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. Prior to initiating treatment with bimekizumab, patients should be evaluated for tuberculosis (TB) infection. Bimekizumab should not be given in patients with active TB and 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

EU summary of product characteristics date of revision December 2022.

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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 8,600 people in approximately 40 countries, the company generated revenue of €5.5 billion in 2022. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

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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,

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