



UCB Reinforces Commitment to Advancing Care in Hidradenitis Suppurativa with Six Abstracts at SHSA 2023

- Results from the Phase 3 studies evaluating impact of bimekizumab on pain and health-related quality of life in moderate to severe hidradenitis suppurativa will be shared in two oral presentations

Brussels (Belgium), 13 October 2023 – 18:00 (CEST) – UCB, a global biopharmaceutical company, today announced that it will present six abstracts in hidradenitis suppurativa (HS) at the 8th Annual Symposium on Hidradenitis Suppurativa Advances (SHSA), October 13–15th in Phoenix, Arizona, U.S. Data and analyses in HS will be presented across two oral presentations and four posters.

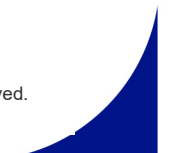
“The data to be presented at SHSA reinforce our commitment to advancing medicines in areas where patients have the greatest need,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. “These new analyses complement and build on the bimekizumab Phase 3 evidence in hidradenitis suppurativa shared to date and further highlight the potential of bimekizumab for the treatment of this chronic, painful, inflammatory condition.”

An oral presentation will showcase 16-Week data from the BE HEARD I and BE HEARD II Phase 3 studies evaluating the impact of bimekizumab on pain in moderate to severe HS. In a second oral presentation, 48-Week data evaluating the impact of bimekizumab on health-related quality of life will be shared. Three poster presentations will include subgroup analyses from the two Phase 3 studies, including 48 Week data in U.S. patients. A disease-focused poster presentation will share barriers to accessing timely and adequate treatment, care and resources for HS patients in select U.S. states.

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.

UCB-sponsored data presentations at SHSA 2023

- Bimekizumab in Moderate to Severe Hidradenitis Suppurativa: 48-Week HiSQoL data from BE HEARD I & II
Kirby JS, Jemec GB, Thorlacius L, Garg A, Kimball AB, Roller R, Muller E, Lambert J, Ingram JR
Oral presentation: Saturday, October 14, 16:05–16:15 MST
- Bimekizumab Impact on Pain in Moderate to Severe Hidradenitis Suppurativa: Week 16 Results from BE HEARD I & II
Orenstein LAV, Shi V, Lev-Tov H, Prens E, Podda M, Fujita H, Lambert J, Roller R, Muller E, Szepietowski JC
Oral presentation: Saturday, October 14, 16:35–16:45 MST
- Bimekizumab in Black/African-American Patients with Moderate to Severe Hidradenitis Suppurativa in BE HEARD I & II





Mayo T, Chovatiya R, Shi V, Naik HB, Benhadou F, Costanzo A, Davis L, Lambert J, Rolleri R, Zouboulis CC
Poster

- Bimekizumab in Patients with Moderate to Severe Hidradenitis Suppurativa by Subgroup: Week 16 Data from BE HEARD I & II
Naik HB, Hsiao J, Porter M, Reguiai Z, Martorell A, Frew JW, Pansar I, Rolleri R, Tilt N, Lambert J, Kirby B
Poster
- Bimekizumab in Moderate to Severe Hidradenitis Suppurativa: 48-Week Efficacy in US Patients from BE HEARD I & II
Gottlieb AB, Mayo T, Sayed C, Kirby JS, Garg A, Oh T, Gomez B, Dokhe P, Rolleri R, Davis L, Daveluy
Poster
- Barriers to Accessing Timely and Adequate Treatment, Care, and Resources for Patients with HS in Select US States
Daveluy S, Brooks B, Hazelett B, Hamzavi I, DiSalvo A, Schmidt T, Marchi D, McClung L, Beaty S, Espy
JI, Goldberg S
Poster

Notes to editors:

About Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa (HS) is a chronic, recurring, painful, and debilitating inflammatory skin disease, that is associated with systemic manifestations.^{1,2} 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.^{1,2} People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.^{1,2} HS, most commonly develops in early adulthood and affects approximately one percent of the population in most studied countries.^{1,2} 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.^{1,2} 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.³ 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.⁴

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}

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.⁷ 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.⁸





- **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).⁸
- **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.⁸

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.

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 reactions ($\geq 1/100$ 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.

Last accessed: October 2023.

*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

Brand Communications

Eimear O'Brien

T: +32.2.559.92.71

email eimear.obrien@ucb.com

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 8,700 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.

Forward looking statements

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, 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.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

UCB is providing this information, including forward-looking statements, only as of the date of this press release. UCB expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.

References

1. Jemec GBE. Clinical practice. Hidradenitis suppurativa. *N Engl J Med*. 2012;366(2):158–64.
2. Sabat R, Jemec GBE, Matusiak L, et al. Hidradenitis suppurativa. *Nat Rev Dis Primers*. 2020;6(1):18.
3. Koumaki D, Efthymiou O, Bozi E, et al. Perspectives On Perceived Stigma And Self-Stigma In Patients With Hidradenitis Suppurativa. *Clin Cosmet Investig Dermatol*. 2019;12:785–90.
4. Kokolakis G, Wolk K, Schneider-Burrus S, et al. Delayed Diagnosis of Hidradenitis Suppurativa and Its Effect on Patients and Healthcare System. *Dermatology*. 2020;236(5):421–30.
5. ClinicalTrials.gov. NCT04242446. <https://clinicaltrials.gov/ct2/show/NCT04242446>. Last accessed: October 2023.
6. ClinicalTrials.gov. NCT04242498. <https://clinicaltrials.gov/ct2/show/NCT04242498>. Last accessed: October 2023.
7. Glatt S, Helmer E, Haier B, et al. First-in-human randomized study of bimekizumab, a humanized monoclonal antibody and selective dual inhibitor of IL-17A and IL-17F, in mild psoriasis. *Br J Clin Pharmacol*. 2017;83(5):991–1001.
8. BIMZELX® (bimekizumab) EU Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Last accessed: October 2023.

