



UCB receives European Commission approval for BIMZELX[®] ▼ (bimekizumab) as the first IL-17A and IL-17F biologic for moderate to severe hidradenitis suppurativa

- Marketing authorization in the European Union (EU) represents the first regulatory approval worldwide for bimekizumab in the treatment of moderate to severe hidradenitis suppurativa, and its fourth approved indication within the EU
- Approval is supported by data from two Phase 3 studies, BE HEARD I and BE HEARD II, in which bimekizumab significantly improved the signs of disease compared with placebo at Week 16, which were sustained to Week 48, and was well-tolerated
- Hidradenitis suppurativa is a chronic, relapsing and painful inflammatory skin disease with a significant unmet clinical need for which there are few approved treatment options

Brussels (Belgium), 22 April 2024 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced that the European Commission (EC) has granted marketing authorization for BIMZELX[®] (bimekizumab) for the treatment of active moderate to severe hidradenitis suppurativa (HS) in adults with an inadequate response to conventional systemic HS therapy.¹ The approval follows a positive opinion issued in March 2024 by the Committee for Medicinal Products for Human Use of the European Medicines Agency. The EC approval was granted based on results from two Phase 3 studies, BE HEARD I and BE HEARD II, which evaluated the efficacy and safety of bimekizumab in the treatment of moderate to severe HS.

“The European Commission’s approval of bimekizumab marks a significant milestone for the EU hidradenitis suppurativa community, particularly considering the limited treatment options currently available,” said Prof. Dr. Christos C. Zouboulis, President of the European Hidradenitis Suppurativa Foundation (EHSF) e.V. and Director of the Departments of Dermatology, Venereology, Allergology and Immunology, Städtisches Klinikum Dessau, Brandenburg Medical School, Germany. “As a community, we strive to improve the management of hidradenitis suppurativa. Bimekizumab offers a promising new therapeutic option for moderate to severe disease, supported by Phase 3 evidence that demonstrated clinically meaningful and sustained responses over 48 weeks.”

HS is a chronic, relapsing inflammatory skin disease that manifests as nodules, abscesses and pus-discharging fistulas, i.e., channels leading out of the skin, typically in the armpits, groin, and buttocks.^{2,3} HS typically starts in early adulthood and affects approximately one percent of the population in most studied countries.^{2,3} HS is associated with significant co-morbidities and can have a profound negative effect on patients’ quality of life.^{2,3}

“Hidradenitis suppurativa can have a devastating impact on people, especially those with moderate to severe disease. In addition to the physical symptoms, there can also be a considerable psychological burden for many people, resulting in a reduced quality of life and missing out on important life events,” said Barry McGrath, Ph.D., Co-Founder of HS Ireland, an association for all people affected by hidradenitis suppurativa in Ireland. “The possibility of a new treatment option to help people living with this disease is most welcome.”



"We are proud to bring the first and only approved medicine targeting IL-17A and IL-17F to the hidradenitis suppurativa community. We believe that bimekizumab has the potential to transform care for people living with moderate to severe disease," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S. "Today's approval signifies the expansion of bimekizumab to its fourth approved indication within the European Union. This milestone achievement underscores our unwavering commitment to raising standards of care across a spectrum of IL-17 mediated diseases."

Notes to editors:

About BE HEARD I and BE HEARD II¹

BE HEARD I and BE HEARD II were multicenter, randomized, double-blind, placebo-controlled Phase 3 studies designed to evaluate the efficacy and safety of bimekizumab in adults with moderate to severe hidradenitis suppurativa (HS). The two studies had a combined enrolment of 1,014 adult patients with a diagnosis of moderate to severe HS. The primary endpoint in both studies was HiSCR50 at Week 16. A key secondary endpoint was HiSCR75 at Week 16. 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.

Results from BE HEARD I and BE HEARD II showed that a significantly higher proportion of patients treated with bimekizumab versus placebo achieved a 50 percent or greater improvement in HS signs and symptoms at Week 16, as measured by HiSCR50, the primary endpoint in both trials. Bimekizumab treatment also resulted in clinically meaningful improvements in the ranked key secondary endpoint, HiSCR75 versus placebo at Week 16. Responses were maintained to Week 48. The safety profile of bimekizumab was consistent with safety data seen in previous trials with no new observed safety signals.

About BIMZELX[®] (bimekizumab)

BIMZELX[®] (bimekizumab) is a humanized monoclonal IgG1 antibody designed to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), two key cytokines driving inflammatory processes.^{1,4} The therapeutic indications in the EU are:¹

- Plaque psoriasis: Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
- 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).
- 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.
- Hidradenitis suppurativa: Bimekizumab is indicated for the treatment of active moderate to severe hidradenitis suppurativa (HS; acne inversa) in adults with an inadequate response to conventional systemic HS therapy.



BIMZELX® ▼ (bimekizumab) EU/EEA* Important Safety Information¹

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%, 14.6%, 16.3%, 8.8% in plaque psoriasis, psoriatic arthritis, axial spondyloarthritis (axSpA) and hidradenitis suppurativa, respectively) and oral candidiasis (7.3%, 2.3%, 3.7%, 5.6% in PSO, PsA, axSpA and HS, respectively). Common adverse reactions ($\geq 1/100$ to $< 1/10$) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, vulvovaginal mycotic infection (including vulvovaginal candidiasis), 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 to 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: April 2024. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

*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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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 9,000 people in approximately 40 countries, the company generated revenue of €5.3 billion in 2023. 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, 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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