UCB News

UCB Announces EU Regulatory Filing for Bimekizumab for the Treatment of Moderate to Severe Hidradenitis Suppurativa

- Regulatory filing supported by data from two bimekizumab Phase 3 studies in hidradenitis suppurativa
- Hidradenitis suppurativa is a chronic, painful, inflammatory skin condition that is associated with systemic manifestations, and affects approximately 1 in 100 people

Brussels (Belgium), 18th July 2023 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced that the European Medicines Agency (EMA) has accepted for review the marketing authorization application for bimekizumab, an IL-17A and IL-17F inhibitor, for the treatment of adults with moderate to severe hidradenitis suppurativa (HS).

"This EU regulatory submission for bimekizumab reflects our pursuit to address unmet patient needs and to advance standards of care in hidradenitis suppurativa, especially given that few treatment options are available today. If approved, this would represent the fourth indication for bimekizumab in the European Union across a range of IL-17 mediated diseases," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

The application for HS is supported by data from the Phase 3 BE HEARD I and BE HEARD II studies which were previously communicated.[1] In both studies, bimekizumab demonstrated statistically significant and clinically meaningful improvements over placebo in signs and symptoms of HS at week 16, as measured by HiSCR50, the primary endpoint in the two studies, with maintained response to Week 48.[1*] Patients treated with bimekizumab also achieved deep levels of clinical response with a greater proportion achieving HiSCR75, a key secondary endpoint, at week 16 than placebo.[1] The safety profile of bimekizumab across BE HEARD I and BE HEARD II was consistent with previous bimekizumab studies with no new safety signals observed.[1]

In August 2021, bimekizumab▼ first received marketing authorization in countries of the European Union (EU)/European Economic Area (EEA) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[2] In June 2023, bimekizumab was approved in countries of the EU/EEA for the treatment of adults with active psoriatic arthritis, and for the treatment of adults with active axial spondyloarthritis (axSpA), including non-radiographic axSpA and ankylosing spondylitis, also known as radiographic axSpA.[2]

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.

Notes to editors:

*p=0.006 and p=0.003 for BE HEARD I and BE HEARD II, respectively with bimekizumab every two weeks (Q2W); p=0.030 and p=0.004 for BE HEARD I and BE HEARD II, respectively with bimekizumab every four weeks (Q4W).

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About Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa (HS) is a chronic, recurring, painful, and debilitating inflammatory skin disease, that is associated with systemic manifestations.[3,4] 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.[3,4] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[3,4]

HS develops in early adulthood, affects approximately one percent of the population in most studied countries.[3,4] 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.[5]

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.[6] 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.[3,5]

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).[7] 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.[8] The two studies had a combined enrolment of 1,014 participants with a diagnosis of moderate to severe HS.[7,8] The primary endpoint in both studies was HiSCR50 at week 16.[8] 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.[7,8] The two studies 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.[7,8]

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.[9] 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.[2]
- **Psoriatic arthritis:** Bimekizumab is indicated alone or in combination with methotrexate, 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).[2]
- **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.[2]

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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 (≥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.

European SmPC date of revision: June 2023.
http://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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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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References

1. Kimball AB, Zouboulis CC, Sayed C, et al. Bimekizumab in patients with moderate-to-severe hidradenitis suppurativa: 48-week efficacy and safety from BE HEARD I & II, two phase 3, randomized, double-blind, placebo controlled, multicenter studies. Late-Breaking Platform Presentation at the 2023 American Academy of Dermatology Annual Meeting.
2.BIMZELX (bimekizumab) EU Summary of Product Characteristics. Available at: http://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdfhttps://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf Last accessed: July 2023
3. Jemec GBE. Clinical practice. Hidradenitis suppurativa. N Engl J Med. 2012;366(2):158-164.
4. Sabat R, Jemec GBE, Matusiak L, et al. Hidradenitis suppurativa. Nat Rev Dis Primers. 2020;6:18.
5. Kokolakis G, Wolk K, Schneider-Burrus S, et al. Delayed Diagnosis of Hidradenitis Suppurativa and Its Effect on Patients and Healthcare System. Dermatology. 2020;236:421–430.
6. Koumaki D, Ourania E, Bozi E, et al. Perspectives On Perceived Stigma And Self-Stigma In Patients With Hidradenitis Suppurativa. Clin Cosmet Investig Dermatol. 2019;12:785–790.
7. ClinicalTrials.gov. A Study to Evaluate the Efficacy and Safety of Bimekizumab in Study Participants With Moderate to Severe Hidradenitis Suppurativa (BE HEARD I). Available at: https://clinicaltrials.gov/ct2/show/NCT04242446?term=be+heard&draw=2&rank=1. Last accessed: July 2023
8. ClinicalTrials.gov. A Study to Evaluate the Efficacy and Safety of Bimekizumab in Study Participants With Moderate to Severe Hidradenitis Suppurativa (BE HEARD II). Available at: https://clinicaltrials.gov/ct2/show/NCT04242498 Last accessed: July 2023
9. 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.

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