UCB News

FDA Accepts Supplemental Biologics License Applications for BIMZELX® (bimekizumab-bkzx) for Moderate to Severe Hidradenitis Suppurativa and Additional 2mL Device Presentations

- Application in moderate to severe hidradenitis suppurativa based on results from two Phase 3 studies where bimekizumab-bkzx showed clinically meaningful improvements vs. placebo at Week 16 which were sustained to Week 48
- Application for the additional bimekizumab-bkzx 2mL device presentations aims to provide more options to optimize the individual patient experience

Brussels (Belgium), April 4, 2024 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the supplemental Biologics License Application (sBLA) for BIMZELX® (bimekizumab-bkzx), an IL-17A and IL-17F inhibitor, for the treatment of adults with moderate to severe hidradenitis suppurativa (HS). In addition, a second sBLA for the bimekizumab-bkzx 2mL device presentations has also been accepted.

"We are excited to share the progress on our FDA applications. The most recent sBLA seeks approval for bimekizumab-bkzx in moderate to severe hidradenitis suppurativa, and is aligned to our goal of expanding the reach of bimekizumab to more patients living with IL-17 mediated diseases," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions, and Head of U.S., UCB. "In addition, the sBLA for the 2mL device presentations aims to offer increased convenience for patients. Today, one dose of bimekizumab in moderate to severe plaque psoriasis, is administered as two 1mL injections. Approval of the 2mL device presentations would mean that patients would have an alternative one injection regimen option."

These new regulatory milestones represent two of five sBLAs accepted by the FDA for bimekizumab-bkzx in 2024, following the previously announced applications in psoriatic arthritis (PsA), non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS). BIMZELX® was first approved in the U.S. in October 2023 for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[1] Bimekizumab-bkzx is not approved in the U.S. for the treatment of moderate to severe HS, PsA, nr-axSpA and AS, or for the 2mL device presentation. In the U.S., the efficacy and safety of bimekizumab-bkzx in the treatment of moderate to severe HS, PsA, nr-axSpA and AS have not been established and these are investigational indications only.

The sBLA in moderate to severe HS is supported by data from the Phase 3 BE HEARD I and BE HEARD II studies where bimekizumab-bkzx demonstrated clinically meaningful improvements in HiSCR50 vs. placebo at Week 16, the primary endpoint.[2] A greater proportion of patients treated with bimekizumab vs. placebo also achieved HiSCR75 at Week 16, a key secondary endpoint.[2] In addition, over 48 weeks, improvements increased for patients in these studies.[2] The safety profile of bimekizumab-bkzx was consistent with previous studies with no new safety signals observed.[2]

The sBLA for the additional device presentations seeks approval of bimekizumab-bkzx 2mL safety syringe and 2mL autoinjector with the aim of providing a second option to the currently approved 1mL presentations.

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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.[3,4] The main symptoms are nodules, abscesses, and pus-discharging tunnels (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. HS develops in early adulthood and affects approximately one percent of the population in most studied countries.[3,4]

About BE HEARD I and BE HEARD II

The efficacy and safety of bimekizumab-bkzx were evaluated in adult patients with moderate to severe hidradenitis suppurativa (HS) in two multicentre, randomized, double-blind, placebo-controlled Phase 3 studies (BE HEARD I and BE HEARD II). 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 trials was HiSCR50 at Week 16.[5,6] 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.[5,6]

About BIMZELX®

BIMZELX® 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]

In the U.S., bimekizumab-bkzx is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[1] Bimekizumab-bkzx is not approved in the U.S. for the treatment of moderate to severe HS, PsA, nr-axSpA and AS, or for the 2mL device presentation. In the U.S., the efficacy and safety of bimekizumab-bkzx in the treatment of moderate to severe HS, PsA, r-axSpA and AS have not been established and these are investigational indications only.

Bimekizumab is not approved in HS by any regulatory authority worldwide.

The approved indications for bimekizumab▼ in the European Union are[8]:

- 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.

The label information may differ in other countries where approved. Please check local prescribing information.

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BIMZELX® U.S. IMPORTANT SAFETY INFORMATION[1]

Please see Important Safety Information below and full U.S. prescribing information at www.ucb-usa.com/Innovation/Products/Bimzelx

Suicidal Ideation and Behavior

BIMZELX® (bimekizumab-bkzx) may increase the risk of suicidal ideation and behavior (SI/B). A causal association between treatment with BIMZELX and increased risk of SI/B has not been established. Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or SI/B. Advise monitoring for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, advise to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.

Infections

BIMZELX may increase the risk of infections. Do not initiate treatment with BIMZELX in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing BIMZELX. Instruct patients to seek medical advice if signs or symptoms suggestive of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, monitor the patient closely and do not administer BIMZELX until the infection resolves.

Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX. Avoid the use of BIMZELX in patients with active TB infection. Initiate treatment of latent TB prior to administering BIMZELX. Consider anti-TB therapy prior to initiation of BIMZELX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients for signs and symptoms of active TB during and after treatment.

Liver Biochemical Abnormalities

Elevated serum transaminases were reported in clinical trials with BIMZELX. Test liver enzymes, alkaline phosphatase and bilirubin at baseline, periodically during treatment with BIMZELX and according to routine patient management. If treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected, interrupt BIMZELX until a diagnosis of liver injury is excluded. Permanently discontinue use of BIMZELX in patients with causally associated combined elevations of transaminases and bilirubin. Avoid use of BIMZELX in patients with acute liver disease or cirrhosis.

Inflammatory Bowel Disease

Cases of inflammatory bowel disease (IBD) have been reported in patients treated with IL-17 inhibitors, including BIMZELX. Avoid use of BIMZELX in patients with active IBD. During BIMZELX treatment, monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.

Immunizations

Prior to initiating therapy with BIMZELX, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with BIMZELX.

Most Common Adverse Reactions

Most common adverse reactions (≥ 1%) are upper respiratory infections, oral candidiasis, headache, injection

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site reactions, tinea infections, gastroenteritis, Herpes Simplex Infections, acne, folliculitis, other Candida infections, and fatigue.

BIMZELX® ▼ (bimekizumab) EU/EEA* Important Safety Information[8]

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: November 2023.

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

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*EU/EEA means European Union/European Economic Area

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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 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.

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, 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.

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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.

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