UCB News

UCB receives U.S. FDA approval for BIMZELX® (bimekizumab-bkzx) as the first IL-17A and IL-17F inhibitor for adults with moderate to severe hidradenitis suppurativa

- Approval is supported by data from the two Phase 3 studies, BE HEARD I and BE HEARD II, in which bimekizumab-bkzx improved the signs and symptoms of disease vs. placebo at Week 16, which were sustained to Week 48
- Hidradenitis suppurativa is a chronic, painful and potentially debilitating inflammatory skin disease
- The milestone marks the fifth indication for bimekizumab-bkzx in the U.S., underscoring UCB's commitment to raising standards of care across a range of IL-17 mediated diseases

Brussels (Belgium), November 20, 2024 – 07:00 (CET) – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved BIMZELX® (bimekizumab-bkzx) for the treatment of adults with moderate to severe hidradenitis suppurativa (HS).[1] Bimekizumab-bkzx is the first and only approved medicine designed to selectively inhibit interleukin 17F (IL-17F) in addition to interleukin 17A (IL-17A).[1]

"The approval of BIMZELX in moderate to severe hidradenitis suppurativa is welcome given the substantial unmet clinical needs and limited number of treatment options available today," said investigator and lead author of the studies, Alexa B. Kimball, MD, MPH, Beth Israel Deaconess Medical Center and Professor of Dermatology, Harvard Medical School, Boston, MA, U.S. "In the Phase 3 clinical studies, patients treated with bimekizumab-bkzx achieved deep and sustained clinical responses up to 48 weeks."

Hidradenitis suppurativa is a chronic, recurring, painful and potentially debilitating inflammatory skin disease.[2,3] The main symptoms are nodules, abscesses and pus-discharging fistulas, i.e., channels leading out of the skin, typically in the armpits, groin and buttocks.[2,3] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[2,3]

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Inspired by patients.
Driven by science.

"We are working toward a world where people with hidradenitis suppurativa live without stigma, feel widely understood and are treated effectively. Today's approval of bimekizumab-bkzx is an exciting time for the hidradenitis suppurativa community, offering a new possibility for the treatment of people in the U.S. living with moderate to severe disease," said Brindley Brooks, Founder and Executive Director, HS Connect, U.S.

The approval is supported by data from two Phase 3 studies, BE HEARD I and BE HEARD II, which evaluated the efficacy and safety of bimekizumab-bkzx in the treatment of adults with moderate to severe HS.[4] Results showed that a higher proportion of patients treated with bimekizumab-bkzx vs. 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.[4] Bimekizumab-bkzx treatment also resulted in clinically meaningful improvements in the key ranked secondary endpoint, HiSCR75, vs. placebo at Week 16.[4] Clinical responses were sustained to Week 48.[4] The safety profile of bimekizumab-bkzx was consistent with safety data seen in previous trials across indications with no new safety signals.[4] Detailed results from BE HEARD I and BE HEARD II have been published in *The Lancet*.[4]

"We are thrilled that with this milestone BIMZELX is now FDA-approved for the treatment of adults with moderate to severe hidradenitis suppurativa, a chronic and painful disease affecting approximately one in 100 people. This is the fifth patient population who may benefit from BIMZELX in the U.S., representing a significant step forward in our mission to alleviate the global burden of immune-mediated inflammatory diseases," said Emmanuel Caeymaex, Executive Vice President, Head of Patient Impact and Chief Commercial Officer, UCB. "This progress underscores our commitment to addressing unmet needs in hidradenitis suppurativa and other immunological conditions, delivering innovative medicines and raising standards of care."

This FDA approval of bimekizumab-bkzx for the treatment of adults with moderate to severe hidradenitis suppurativa follows its recent approvals for the treatment of adults with active psoriatic arthritis, adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation and adults with active ankylosing spondylitis.[1] Bimekizumab-bkzx 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]

Notes to Editors:

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-bkzx in adults with moderate to severe hidradenitis suppurativa (HS).[4] The two studies had a combined

enrolment of 1,014 participants with a diagnosis of moderate to severe HS.[4] The primary endpoint in both studies was HiSCR50 at Week 16.[4] Secondary endpoints included HiSCR75 and HS-specific skin pain response at Week 16.[1,4] 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] Detailed results from these studies are published in *The Lancet*.[4]

About BIMZELX® (bimekizumab-bkzx) in the U.S.
Bimekizumab-bkzx is a humanized IgG1 monoclonal antibody that selectively binds to IL-17A, IL-17F and IL-17AF cytokines, blocking their interaction with the IL-17RA/IL-17RC receptor complex.[1]

Please see Important Safety Information below and full U.S. Prescribing Information at http://www.ucb-usa.com/Innovation/Products/BIMZELX.

BIMZELX U.S. IMPORTANT SAFETY INFORMATION

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 definitively 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, instruct 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, including serious 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,

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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%) in plaque psoriasis and hidradentitis suppurativa include upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes Simplex Infections, acne, folliculitis, other Candida infections, and fatigue.

Most common (≥ 2%) adverse reactions in psoriatic arthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infections.

Most common (≥ 2%) adverse reactions in non-radiographic axial spondyloarthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsillitis, transaminase increase, and urinary tract infections.

Most common (≥ 2%) adverse reactions in ankylosing spondylitis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash, and vulvovaginal mycotic infections.

Please see Important Safety Information below and full U.S. Prescribing Information at www.UCB-USA.com/Innovation/Products/BIMZELX.

About BIMZELX®▼(bimekizumab) in the European Union (EU)/European Economic Area (EEA)

The approved indications for bimekizumab▼ in the EU are:[5]

- 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.

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

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%, 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 (≥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.

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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.

European SmPC date of revision: August 2024. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf.

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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.

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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. 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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