UCB News

BIMZELX® Approved by the U.S. FDA for the Treatment of Adults with Moderate to Severe Plaque Psoriasis

- BIMZELX® (bimekizumab-bkzx) is the first and only IL-17A and IL-17F inhibitor approved for the treatment of adults with moderate to severe plaque psoriasis
- Approval is supported by three Phase 3 trials where bimekizumab consistently delivered fast, complete and lasting levels of skin clearance up to one year, and was generally well tolerated
- UCB expects global peak sales for BIMZELX® of at least €4bn

Brussels (Belgium), 18 OCTOBER 2023 – 07:00 (CEST) – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has approved BIMZELX® (bimekizumab-bkzx) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[1] Bimekizumab is the first and only approved psoriasis treatment designed to selectively inhibit two key cytokines driving inflammatory processes – interleukin 17A (IL-17A) and interleukin 17F (IL-17F).[1] The approval of bimekizumab is supported by data from three Phase 3, multicenter, randomized, placebo and/or active comparator-controlled trials (BE READY, BE VIVID and BE SURE), which evaluated the efficacy and safety of bimekizumab in 1,480 adults with moderate to severe plaque psoriasis.[2,3,4]

"Today's FDA approval for BIMZELX is an exciting milestone that reflects our commitment to continuously improving the standard of care in plaque psoriasis and to raising expectations of what treatment can deliver. We know that completely clear skin is valued by people with psoriasis and, in our Phase 3 trials, at week 16, 85-91% of patients treated with bimekizumab achieved clear or almost clear skin, with 59-68% achieving the goal of complete clearance," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. "With bimekizumab now approved for psoriasis, we will move forward rapidly to submit applications for additional indications in the U.S."

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"We have been eagerly awaiting bimekizumab, the first IL-17A and IL-17F inhibitor, to be approved in the U.S. for the treatment of adults with moderate to severe plaque psoriasis. In Phase 3/3b trials, bimekizumab achieved superior levels of skin clearance at week 16 compared to placebo and three existing biologics for psoriasis, with responses being rapid and lasting up to a year. Long-term data have also shown that the majority of patients maintained high levels of clinical response through three years," said Mark Lebwohl, MD, bimekizumab investigator, Dean for Clinical Therapeutics, Icahn School of Medicine at Mount Sinai, and Chairman Emeritus, Kimberly and Eric J. Waldman Department of Dermatology.

Psoriasis affects more than 7.5 million adults in the U.S. and impacts much more than the skin itself.[5] In addition to the recognized skin symptoms such as itching and flaking, psoriasis can place strains on patients and their families, impacting work, relationships and home lives.[6,7] A U.S. observational study (n=846) reported that only one in four patients achieved self-assessed complete skin clearance after six months of treatment with biologics highlighting the burden of plaque psoriasis and the need for additional new treatment options.[8]

The FDA recommended dosage of bimekizumab for psoriasis patients is 320 mg (given as two subcutaneous injections of 160 mg each) at Weeks 0, 4, 8, 12 and 16, then every 8 weeks thereafter.[1] For patients weighing ≥120 kg, a dose of 320 mg every 4 weeks after week 16 may be considered.[1] Bimekizumab may be administered by a healthcare professional, or a patient may self-inject after proper training.[1] Bimekizumab is available as an autoinjector and a pre-filled syringe.[1] Bimekizumab will be available in the U.S. in approximately one month.

"The approval of bimekizumab will provide an important new treatment option for adults living with moderate to severe plaque psoriasis," said Leah McCormick Howard, J.D., President and CEO for the National Psoriasis Foundation. "Our hope is that new treatments translate into improved outcomes for many and help alleviate the physical and emotional burden of psoriasis."

Jean-Christophe Tellier, CEO, UCB added, "We are pleased to deliver new options for people living with severe diseases as part of an unprecedented series of product launches from UCB around the world. Delivering these solutions draws on our scientific expertise and understanding of disease biology and our legacy of deep understanding of patients to provide differentiated treatments. Our continued work embodies what UCB stands for – that we are inspired by patients, driven by science."

UCB expects global peak sales for BIMZELX of at least €4bn.

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Key Findings from the Phase 3 Clinical Development Program

The efficacy and safety of bimekizumab were evaluated in three Phase 3 studies, versus placebo and ustekinumab (BE VIVID), versus placebo (BE READY) and versus adalimumab (BE SURE).[2,3,4] All studies met their co-primary endpoints and all ranked secondary endpoints.[2,3,4]

Patients treated with bimekizumab achieved superior levels of skin clearance at week 16, compared to those who received ustekinumab (ranked secondary endpoint, BE VIVID; $p<0.0001$), placebo (co-primary endpoint, BE READY and BE VIVID; $p<0.0001$) and adalimumab (co-primary endpoint, BE SURE; $p<0.001$), as measured by at least a 90 percent improvement in the Psoriasis Area & Severity Index (PASI 90) and an Investigator's Global Assessment (IGA) response of clear or almost clear skin (IGA 0/1).[2,3,4] Ranked secondary endpoints included PASI 75 at week 4 and PASI 100 (complete skin clearance) at week 16.[2,3,4] Key findings across all studies include:

- **Clear or Almost Clear Skin:** More than eight out of 10 patients receiving bimekizumab (320 mg every four weeks [Q4W]) achieved PASI 90 and IGA 0/1 at week 16.[2,3,4]
- **Complete Skin Clearance:** Approximately six out of 10 patients receiving bimekizumab (320 mg Q4W) achieved PASI 100 at week 16.[2,3,4]
- **Speed of Response:** Clinical responses achieved with bimekizumab were rapid, with more than seven out of 10 patients achieving PASI 75 at week 4 following one dose (320 mg).[2,3,4]
- **Maintenance of Response:** Clinical responses achieved with bimekizumab at week 16 (PASI 90 and PASI 100) were maintained for up to one year.[2,3,4] Long-term data showed that clinical responses were maintained in the vast majority of patients through to three years of bimekizumab treatment.[9]

The most common adverse reactions (≥ 1%) are upper respiratory infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes Simplex Infections, acne, folliculitis, other Candida infections, and fatigue.[1]

Notes to Editors:

Dr. Lebwohl is an investigator for UCB. He has not accepted any consulting payments from UCB.

About BIMZELX (bimekizumab-bkzx)

Bimekizumab 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] Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin.[1]

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UCB News

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

BIMZELX U.S. IMPORTANT SAFETY INFORMATION

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 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.

GL-BK-2300019

Date of preparation: October 2023

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

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.

GL-BK-2300019
Date of preparation: October 2023

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

*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 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, 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.

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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