UCB News

First presentation of four-year BIMZELX® (bimekizumab-bkzx) data showed long-term maintenance of complete skin clearance in moderate to severe plaque psoriasis

- Late-breaking platform presentation showed that bimekizumab-bkzx rapidly achieved and maintained high rates of clinical and health-related quality-of-life responses through four years; six out of ten patients achieved complete skin clearance at Year 4
- Responder-analyses demonstrated that approximately nine out of ten patients treated with bimekizumab-bkzx who achieved PASI90 at Week 16, and over seven out of ten patients who achieved complete skin clearance (PASI100) maintained their response to Year 4
- Four-year safety data showed that treatment-emergent adverse events were consistent or decreased with longer bimekizumab-bkzx exposure, with no new safety signals

Brussels (Belgium), 9 March 2024 – 18:00 (CET) – UCB, a global biopharmaceutical company, today announced that the first presentations of BIMZELX® (bimekizumab-bkzx) four-year efficacy and safety data in the treatment of adults with moderate to severe plaque psoriasis are being shared this week at the 2024 American Academy of Dermatology (AAD) Annual Meeting in San Diego, California, U.S., March 8–12.

"We are proud to debut the BIMZELX® four-year psoriasis data at the world's largest dermatology meeting, showing that the majority of adult patients treated with bimekizumab-bkzx achieved deep and durable clinical response through four years, with a consistent tolerability profile. These results, from the largest pool of Phase 3 data, closely follow the U.S. launch, and reinforce our belief that BIMZELX® has the potential to transform the lives of people with moderate to severe plaque psoriasis," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

"Moderate to severe plaque psoriasis is a chronic condition with physical skin manifestations that can place a significant burden on a patient's health-related quality-of-life. Analysis shows that through four years of bimekizumab-bkzx treatment, over six out of ten patients achieved and maintained complete skin clearance, a clinically meaningful endpoint and outcome for patients. These long-term data will be highly welcomed by the dermatology community since they provide important considerations for clinical practice," said Dr. Bruce Strober, Clinical Professor of Dermatology at Yale University, and Central Connecticut Dermatology, Connecticut, U.S.

The late-breaking platform presentation shared bimekizumab-bkzx pooled data from treatment initiation

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through four years, showing that high rates of clinical and health-related quality-of-life responses were rapidly achieved and were maintained in the long term.[1] Responder-analyses showed that approximately nine out of ten patients treated with bimekizumab-bkzx who achieved ≥90 percent improvement from baseline in the Psoriasis Area Severity Index (PASI90) and over seven out of ten patients who achieved complete skin clearance (PASI100) at Week 16 maintained their responses to Year 4.[2] Pooled analysis from five Phase 3/3b studies showed that bimekizumab-bkzx demonstrated good tolerability and a consistent safety profile with no new safety findings identified up to four years in patients with moderate to severe plaque psoriasis.[3]

Highlights from the four-year bimekizumab-bkzx data in moderate to severe plaque psoriasis presented at the 2024 AAD:

Treatment initiation through four years: Data were pooled across the 52-week BE VIVID study, the 56-week BE READY and BE SURE studies and their open-label extension (OLE Week 144) BE BRIGHT.[1] Analyzed patients were randomized to bimekizumab-bkzx 320 mg every four weeks (Q4W) to Week 16, then bimekizumab-bkzx Q4W or Q8W until OLE entry.[1] Clinical and health-related quality of life (PASI90 and PASI100, body surface area [BSA] ≤1 percent and Dermatology Life Quality Index [DLQI]0/1) responses were assessed through to Year 4 (OLE Week 144).[1] Data are presented below for all patients who received bimekizumab-bkzx continuously from baseline and entered the OLE (n=771):[1]

- 90.9 percent achieved PASI90 at Week 16, and 86.1 percent through to Year 4.[1¥]
- 65.8 percent achieved PASI100 at Week 16, and 64.7 percent through to Year 4.[1¥]
- 78.5 percent achieved BSA≤1 percent at Week 16, and 79.8 percent through to Year 4.[1¥]
- 71.5 percent achieved DLQI0/1 at Week 16, and 78.7 percent through to Year 4.[1 ¥]

Responder analysis to Year 4: Patients who completed the BE VIVID, BE SURE and BE READY Phase 3 studies could enter the BE BRIGHT OLE.[2] Analyzed patients were randomized to bimekizumab-bkzx 320 mg Q4W to Week 16, then bimekizumab-bkzx Q4W or Q8W until OLE entry, then bimekizumab-bkzx Q4W or Q8W dependent on PASI response/prior dose.[2] Maintenance of PASI90 and PASI100 was assessed in Week 16 responders to Year 4 (OLE Week 144) and is presented below for all patients:[2]

- 87.7 percent who achieved PASI90 at Week 16 (n=693) maintained their response to Year 4.[2¥]
- 73.3 percent who achieved PASI100 at Week 16 (n=503) maintained their response to Year 4.[2¥]

Safety and tolerability through four years: Data were pooled across the 52-week BE VIVID study, the 56-week BE READY and BE SURE studies, and the OLE studies BE BRIGHT and BE RADIANT.[3] The total bimekizumab-bkzx exposure was 6,324.3 patient-years (PY) across the studies (n=2,186).[3]

- Exposure-adjusted incidence rates (EAIRs) of treatment-emergent adverse events (TEAEs) remained consistent or decreased with longer bimekizumab-bkzx exposure. Overall, TEAEs occurred at an EAIR of 170.5/100 PY and serious TEAEs at 5.5/100 PY.[3]

GL-BK-2400009
Date of preparation: March 2024

- The most common TEAEs were nasopharyngitis (12.7/100 PY), oral candidiasis (8.9/100 PY), and upper respiratory tract infections (5.7/100 PY). Oral candidiasis decreased from 18.9/100 PY at Year 1 to 5.4/100 PY at Year 4.[3] Throughout, fewer TEAEs occurred with bimekizumab-bkzx every 8 weeks (Q8W) (115.4/100 PY) vs. every 4 weeks (Q4W) (224.4/100 PY).[3]

[¥] *Modified non-responder imputation analyses*

Notes to Editors:

About BIMZELX®

Bimekizumab-bkzx 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.[4]

In the U.S., BIMZLEX® is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[5]

The approved indications for bimekizumab▼ 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.[6]
- **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).[6]
- **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.[6]

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

In the U.S., bimekizumab is not approved for the treatment of psoriatic arthritis or axial spondyloarthritis and these are investigational indications only.

BIMZELX U.S. IMPORTANT SAFETY INFORMATION[5]

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

Suicidal Ideation and Behavior

GL-BK-2400009
Date of preparation: March 2024

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.

GL-BK-2400009
Date of preparation: March 2024

Most Common Adverse Reactions

Most common adverse reactions (≥1 percent) 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[6]

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.

GL-BK-2400009
Date of preparation: March 2024

European SmPC date of revision: November 2023.

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

*EU/EEA means European Union/European Economic Area Last accessed: March 2024.

▼*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

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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

GL-BK-2400009
Date of preparation: March 2024

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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