UCB News

UCB announces U.S. FDA approvals for BIMZELX® (bimekizumab-bkzx) for the treatment of psoriatic arthritis, non-radiographic axial spondyloarthritis and ankylosing spondylitis

- With three new indications, BIMZELX® (bimekizumab-bkzx) is the first and only IL-17A and IL-17F inhibitor approved in the U.S. for the treatment of four chronic immune-mediated inflammatory diseases
- Approval in active PsA is supported by two Phase 3 studies in which bimekizumab-bkzx showed statistically significant improvements vs. placebo at Week 16 in both joint and skin symptoms, across biologic-naïve and TNF inhibitor-inadequate responder populations, which were sustained to Week 52
- Approvals in active nr-axSpA and active AS are supported by two Phase 3 studies, in which bimekizumab-bkzx showed statistically significant improvements vs. placebo in signs and symptoms at Week 16, which were sustained to Week 52

Brussels (Belgium), September 23, 2024 – 07:00 (CEST) – 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 adults with active psoriatic arthritis (PsA), adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, and adults with active ankylosing spondylitis (AS).[1] Bimekizumab-bkzx is the first approved treatment for these three indications that is designed to selectively inhibit two key cytokines driving inflammatory processes – interleukin 17A (IL-17A) and interleukin 17F (IL-17F).[1] These newly approved indications follow the first U.S. approval for BIMZELX® in October 2023 for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[1]

GL-BK-2400099
Date of preparation: September 2024

"The approval of BIMZELX in the U.S. across three new indications – active psoriatic arthritis, active non-radiographic axSpA with objective signs of inflammation, and active ankylosing spondylitis – highlights the clinical benefit of dual inhibition of both IL-17A and IL-17F for patients, and provides an opportunity for more people living with chronic inflammatory diseases to achieve meaningful outcomes," said Emmanuel Caeymaex, Executive Vice President, Head of Patient Impact and Chief Commercial Officer, UCB. "In psoriatic arthritis and across the spectrum of axSpA, clinical study results and real-world experience outside the U.S. have highlighted that BIMZELX can help patients achieve high thresholds of clinical response that are rapid in onset and sustained up to two years."

The FDA recommended dosage of bimekizumab for adult patients with active PsA, active nr-axSpA with objective signs of inflammation, and active AS is 160 mg by subcutaneous injection every four weeks.[1] For PsA patients with co-existent moderate to severe plaque psoriasis, the dosage and administration is the same as for patients with moderate to severe plaque psoriasis.[1] BIMZELX is currently available for eligible patients.

Bimekizumab-bkzx for the treatment of adults with active psoriatic arthritis

"In Phase 3 clinical studies, the clinically meaningful and consistent clinical response in patients who had a previous inadequate response to TNF inhibitors, and in patients who were new to biologics, suggest that bimekizumab-bkzx has the potential to be an important new treatment option in our armamentarium for adults with psoriatic arthritis," said Joseph F. Merola, MD, MMSc, Professor, Dermatologist, Rheumatologist, and Investigator, BE OPTIMAL and BE COMPLETE. "The approval of bimekizumab-bkzx for the treatment of active psoriatic arthritis provides a new, differentiated treatment option for the rheumatology and dermatology communities."

The approval of bimekizumab-bkzx for adult patients with active PsA is supported by data from the Phase 3 BE OPTIMAL and BE COMPLETE studies, in which bimekizumab-bkzx met the primary endpoint of American College of Rheumatology 50 (ACR50) response at Week 16 versus placebo, and all ranked secondary endpoints.[2,3] Consistent results were seen across both biologic-naïve and TNF inhibitor inadequate-responder (TNFi-IR) populations.[2,3] Clinical responses achieved at Week 16 were sustained to Week 52 in BE OPTIMAL and in BE COMPLETE, and its open-label extension, as assessed by ACR50 (primary endpoint), Psoriasis Area and Severity Index 90 (PASI90, ranked secondary endpoint), minimal disease activity (MDA; ranked secondary endpoint) and PASI100, i.e., complete skin clearance (other endpoint).[4,5]

"Psoriatic arthritis can severely impact a person's quality of life. With joint pain and stiffness, daily activities can become burdensome. New treatment options are always a welcome addition, and they offer some renewed hope for relief from the symptoms and health impacts of PsA," said Leah M. Howard, J.D., the President and CEO of the National Psoriasis Foundation, U.S.

GL-BK-2400099
Date of preparation: September 2024

Bimekizumab-bkzx for the treatment of adults with active nr-axSpA and active AS
"In the Phase 3 clinical studies, patients treated with bimekizumab-bkzx saw improvements in signs and symptoms and key measures of disease activity at Week 16 which were sustained to one year and consistent across patients with non-radiographic axial spondyloarthritis and ankylosing spondylitis," said Atul Deodhar, MD, Professor of Medicine and Medical Director of rheumatology clinics at the Division of Arthritis & Rheumatic Diseases, Oregon Health & Science University, Portland, Oregon, U.S. "The U.S. rheumatology community welcomes the approval of bimekizumab-bkzx for use across the entire spectrum of axial spondyloarthritis, especially given that there are few options approved currently to treat both non-radiographic axial spondyloarthritis and ankylosing spondylitis."

The approvals of bimekizumab-bkzx for adult patients with active nr-axSpA with objective signs of inflammation, and active AS are supported by data from the Phase 3 BE MOBILE 1 and BE MOBILE 2 studies, respectively.[6,7] In both studies, bimekizumab-bkzx met the primary endpoint of Assessment of SpondyloArthritis international Society 40 (ASAS40) response at Week 16 compared with placebo, and all ranked secondary endpoints.[6,7] ASAS40 responses were consistent across TNFi-naïve and TNFi-inadequate responder patients.[6,7] Clinical responses achieved at Week 16 were sustained in both patients with nr-axSpA and AS to Week 52 as assessed by ASAS40, ranked secondary and other endpoints.[6,7]

"People living with non-radiographic axial spondyloarthritis and ankylosing spondylitis experience pain, stiffness and fatigue that can limit their daily activities, ability to work, and quality of life," said Seth Ginsberg, Co-Founder and President, Global Health Living Foundation and CreakyJoints, U.S. "A new treatment option offers the opportunity for more patients to reach their treatment goals."

Notes to Editors:

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a serious, highly heterogeneous, chronic, systemic inflammatory condition affecting both the joints and skin, with a prevalence of 0.02 percent to 0.25 percent of the population.[8] PsA affects approximately 30 percent of people living with psoriasis.[9] Symptoms include joint pain and stiffness, skin plaques, swollen toes and fingers (dactylitis), inflammation of the sites where tendons or ligaments insert into the bone (enthesitis), and inflammatory axial involvement.[10]

About BE OPTIMAL and BE COMPLETE[2,3,4,5]

Bimekizumab-bkzx (160 mg every four weeks) was evaluated in adult patients with active psoriatic

GL-BK-2400099
Date of preparation: September 2024

arthritis (PsA) in two Phase 3 multicentre, randomized, double-blind, placebo-controlled studies (BE OPTIMAL and BE COMPLETE). The BE OPTIMAL study evaluated 852 patients not previously exposed to any biologic disease-modifying anti-rheumatic drug (bDMARD-naïve) for the treatment of PsA. The BE COMPLETE study evaluated 400 patients with an inadequate response or intolerance to treatment with one or two tumour necrosis factor alpha inhibitors (TNFi-IR) for the treatment of PsA.

Key findings from the Phase 3 Clinical Development Program:

- **Joint Symptoms, ACR50**: In bDMARD-naive and TNFi-IR patients, 44 percent (n=189/431) and 43 percent (n=116/267) receiving bimekizumab-bkzx achieved ACR50 response (primary endpoint) at Week 16, respectively, versus 10 percent (n=28/281) and 7 percent (n=9/133) receiving placebo (p<0.0001).[2,3] Clinical responses were generally sustained to Week 52.[4,5]
- **Minimal Disease Activity (MDA):** In bDMARD-naive and TNFi-IR populations, 45 percent (n=194/431) and 44 percent (n=118/267) of patients receiving bimekizumab-bkzx achieved MDA (key ranked secondary endpoint) at Week 16, respectively, versus 13 percent (n=37/281) and 6 percent (n=8/133) receiving placebo (p<0.0001). [2,3] Clinical responses were generally sustained to Week 52.[4,5]
- **Skin Symptoms, Complete Skin Clearance (PASI100):** In bDMARD-naive and TNFi-IR populations, 47 percent (n=103/217) and 59 percent (n=103/176) of patients with baseline psoriasis affecting ≥3 percent of surface area receiving bimekizumab-bkzx achieved complete skin clearance (PASI100; other endpoint) at Week 16, respectively, versus 2 percent (n=3/140) and 5 percent (n=4/88) receiving placebo. [2,3] Clinical responses were generally sustained to Week 52.[4,5]

In PsA, the most common (≥ 2 percent) adverse reactions with bimekizumab-bkzx are upper respiratory tract infections, oral candidiasis, headache, diarrhea and urinary tract infection.[1]

About Axial Spondyloarthritis

Axial spondyloarthritis (axSpA), which includes both non-radiographic axSpA (nr-axSpA) and ankylosing spondylitis (AS), also known as radiographic axSpA (r-axSpA), is a chronic, immune-mediated, inflammatory disease.[11] Non-radiographic-axSpA (nr-axSpA) is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.[11] axSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).[11] The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise, but not with rest.[11] Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease, and dactylitis.[11] The overall prevalence of axSpA is up to 1.4 percent of adults.[12,13] Approximately half of

GL-BK-2400099
Date of preparation: September 2024

all patients with axSpA are patients with nr-axSpA.[11] Axial spondyloarthritis onset usually occurs before the age of 45.[11] Approximately 10 to 40 percent of patients with nr-axSpA progress to ankylosing spondylitis over 2 to 10 years.[11]

About BE MOBILE 1 and BE MOBILE 2[6,7]

The efficacy and safety of bimekizumab, 160 mg every four weeks, were evaluated in two Phase 3 multicenter, randomized, double-blind, placebo-controlled studies, one in non-radiographic axSpA (nr-axSpA; BE MOBILE 1) and one in ankylosing spondylitis (AS; BE MOBILE 2). The BE MOBILE 1 and BE MOBILE 2 studies evaluated 254 and 332 patients, respectively.

Key findings from the Phase 3 BE MOBILE 1 and BE MOBILE 2 studies:

- **ASAS40**: In nr-axSpA and AS populations, 47.7 percent (n=61/128) and 44.8 percent (n=99/221), respectively, of patients receiving bimekizumab-bkzx achieved the primary endpoint of ASAS40 response at Week 16, versus 21.4 percent (n=27/126) and 22.5 percent (n=25/111) receiving placebo ($p<0.001$).[6] Clinical responses were sustained to Week 52, with consistent outcomes across both TNFi-naïve and TNFi-inadequate responder populations.[7]
- **Low Disease Activity**: Low disease activity (Ankylosing Spondylitis Disease Activity Score (ASDAS) <2.1, an exploratory endpoint) was achieved at Week 16 by 46.2 percent of patients with nr-axSpA and 44.9 percent of patients with AS versus 20.6 percent and 17.5 percent in the placebo group.[6] In the two studies, approximately 6 out of 10 patients treated with bimekizumab-bkzx achieved ASDAS<2.1 by Week 52.[7]
- **Inflammation**: Sustained reduction of objective inflammatory signs in both sacroiliac joints and the spine was observed in patients with nr-axSpA and patients with AS treated with bimekizumab-bkzx versus placebo as assessed by magnetic resonance imaging at Week 16 and Week 52, an exploratory endpoint.[6,7]

In nr-axSpA, the most common (≥ 2 percent) adverse reactions with bimekizumab-bkzx are upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsilitis, transaminase increase and urinary tract infection.[1]

In AS, the most common (≥ 2 percent) adverse reactions with bimekizumab-bkzx are upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash and vulvovaginal mycotic infection.[1]

GL-BK-2400099
Date of preparation: September 2024

About BIMZELX in the U.S. (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]

Please see Important Safety Information below and full U.S. Prescribing Information at 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 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.

GL-BK-2400099
Date of preparation: September 2024

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 (≥ 1%) adverse reactions in plaque psoriasis 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 infection.

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 infection.

GL-BK-2400099
Date of preparation: September 2024

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

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

The approved indications for bimekizumab▼ in the EU are:[14]

- Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
- 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).
- 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.
- 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

GL-BK-2400099
Date of preparation: September 2024

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.

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.

Last accessed: September 2024.

GL-BK-2400099
Date of preparation: September 2024

UCB News

▼ 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.

For further information, contact UCB:

Investor Relations
Antje Witte
T +32.2.559.94.14
email antje.witte@ucb.com

Corporate Communications
Laurent Schots
T +32.2.559.92.64
email laurent.schots@ucb.com

Brand Communications
Scott Fleming
Tel: +44 175 344 7515
Email: Scott.Fleming@ucb.com

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

GL-BK-2400099
Date of preparation: September 2024

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.

UCB is providing this information, including forward-looking statements, only as of the date of this press release. UCB expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.

References

1. BIMZELX® (bimekizumab-bkzx) U.S. Prescribing Information. https://www.ucb-usa.com/Innovation/Products/BIMZELX. Accessed on September 2024.
2. McInnes IB, Asahina A, Coates LC, et al. Bimekizumab in patients with psoriatic arthritis, naïve to biologic treatment: a randomised, double-blind, placebo-controlled, phase 3 trial (BE OPTIMAL). Lancet. 2023;401(10370):25–37.
3. Merola JF, Landewé R, McInnes IB, et al. Bimekizumab in patients with active psoriatic arthritis and previous inadequate response or intolerance to tumour necrosis factor-α inhibitors: a randomised, double-blind, placebo-controlled, phase 3 trial (BE COMPLETE). Lancet. 2023;401(10370):38–48.
4. Ritchlin CT, Coates LC, McInnes IB, et al. Bimekizumab treatment in biologic DMARD-naïve patients with active psoriatic arthritis: 52-week efficacy and safety results from the phase III, randomised, placebo-controlled, active reference BE OPTIMAL study. Ann Rheum Dis. 2023;82:1404–14.
5. Coates LC, Landewé R, McInnes IB, et al. Bimekizumab treatment in patients with active psoriatic arthritis and prior inadequate response to tumour necrosis factor inhibitors: 52-week safety and efficacy from the phase III BE COMPLETE study and its open-label extension BE VITAL. RMD Open. 2024;10:e003855.
6. van der Heijde D, Deodhar A, Baraliakos X, et al. Efficacy and safety of bimekizumab in axial spondyloarthritis: results of two parallel phase 3 randomized controlled trials. Ann Rheum Dis. 2023;82:515–26.
7. Baraliakos X, Deodhar A, van der Heijde D, et al. Bimekizumab treatment in patients with active axial spondyloarthritis: 52-week efficacy and safety from the randomised parallel phase 3 BE MOBILE 1 and BE MOBILE 2 studies. Ann Rheum Dis. 2024;83(2):199–213.
8. Ogdie A, Weiss P. The Epidemiology of Psoriatic Arthritis. Rheum Dis Clin North Am. 2015;41(4):545–68.

GL-BK-2400099
Date of preparation: September 2024

9. Mease PJ, Gladman DD, Papp KA, et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. J Am Acad Dermatol. 2013;69(5):729-735. doi: 10.1016/j.jaad.2013.07.023.
10. Mease PJ, Armstrong AW. Managing patients with psoriatic disease: the diagnosis and pharmacologic treatment of psoriatic arthritis in patients with psoriasis. Drugs. 2014;74:423–41.
11. Deodhar A. Understanding Axial Spondyloarthritis: A Primer for Managed Care. Am J Manag Care. 2019;25:S319-30.
12. Reveille J, Witter J, Weisman M. Prevalence of axial spondylarthritis in the United States: estimates from a cross-sectional survey. Arthritis Care Res. 2012;64(6):905–10.
13. Hamilton L, Macgregor A, Toms A, et al. The prevalence of axial spondyloarthritis in the UK: a cross-sectional cohort study. BMC Musculoskelet Disord. 2015;16:392.
14. BIMZELX® (bimekizumab) EU SmPC. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Accessed on September 2024.

GL-BK-2400099
Date of preparation: September 2024