UCB News

UCB to share first presentations of BIMZELX® ▼(bimekizumab) two-year data in axial spondyloarthritis and psoriatic arthritis at EULAR 2024

- Patients with non-radiographic axial spondyloarthritis (nr-axSpA) and those with radiographic axSpA (r-axSpA) treated with bimekizumab showed sustained and consistent clinical and patient-reported outcomes up to two years
- Late-breaking data revealed that >90 percent of r-axSpA patients treated with bimekizumab showed no spinal radiographic progression over two years, as defined by modified Stoke Ankylosing Spondylitis Spinal Score change from baseline <2
- Patients with psoriatic arthritis treated with bimekizumab who were new to biologics, and those with prior inadequate response or intolerance to tumour necrosis factor inhibitors, showed sustained and consistent minimal disease activity up to two years

Brussels (Belgium), 12 June 2024 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced the first presentation of two-year data from the Phase 3 studies, BE MOBILE 1 and BE MOBILE 2, and the open-label extension, BE MOVING, evaluating bimekizumab, an IL-17A and IL-17F inhibitor, in the treatment of active non-radiographic axial spondyloarthritis (nr-axSpA) and active radiographic axSpA (r-axSpA). The impact of bimekizumab treatment on two-year radiographic progression in the spine of patients with r-axSpA will also be presented in a late-breaking oral presentation. In addition, the first two-year bimekizumab data in psoriatic arthritis from the Phase 3 studies, BE OPTIMAL and BE COMPLETE, and the open-label extension, BE VITAL, are also announced today. These data are presented at the European Congress of Rheumatology, EULAR 2024, in Vienna, Austria, June 12–15.[1,2,3,4]

"The bimekizumab new two-year data in axial spondyloarthritis and psoriatic arthritis presented at EULAR 2024 reinforce our belief in bimekizumab to provide long-term robust and sustained outcomes for patients with psoriatic arthritis and for patients across the full spectrum of axial spondyloarthritis," said Emmanuel Caeymaex, Executive Vice President, Head of Patient Impact, Chief Commercial Officer, UCB. "We are particularly excited to share new late-breaking data that highlights our commitment to demonstrate the long-term benefit of bimekizumab on disease progression in radiographic axial spondyloarthritis."

"The bimekizumab data in axial spondyloarthritis presented at EULAR 2024 showed that non-radiographic and radiographic axSpA patients achieved sustained suppression of inflammation over two years, and reported sustained improvements in symptoms which have a substantial impact on daily living including spinal pain, morning stiffness and fatigue," said Xenofon Baraliakos, Professor of Internal Medicine and Rheumatology, Ruhr-University Bochum, Bochum, Germany. "One of the long-term treatment goals in axSpA is the prevention of structural progression. Late-breaking data also shared at the congress showed that the majority of radiographic axial spondyloarthritis patients treated with bimekizumab had no spinal radiographic progression over two years."

"Minimal disease activity and remission are key treatment targets in the treatment of psoriatic arthritis," said Laura Coates, Associate Professor, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, UK. "New two-year data presented at EULAR 2024 showed that approximately

50% of patients treated with bimekizumab achieved sustained minimal disease activity and remission over two years. Improvements were observed across all patient-reported and most clinical components of minimal disease activity, with robust improvements in joint and skin outcomes."

Across the spectrum of axSpA, approximately one in two patients treated with bimekizumab over two years achieved and maintained a 40 percent or greater improvement in signs and symptoms of axSpA (Assessment of SpondyloArthritis international Society (ASAS40).[1†] At two years, approximately six in ten patients with nr-axSpA and r-axSpA achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) low disease activity (ASDAS <2.1) and three in ten achieved a state of inactive disease (ASDAS <1.3).[1‡] Late-breaking data revealed that patients with r-axSpA treated with bimekizumab showed minimal spinal radiographic progression at two years, and there was a high proportion of non-progressors, including in those with baseline spinal damage. Furthermore, one-year results and post hoc analyses from BE MOBILE 1 and BE MOBILE 2 showed that treatment with bimekizumab substantially improved magnetic resonance imaging (MRI) inflammation, reduced erosions and increased backfill and fat in the sacroiliac joints of patients with nr-axSpA and r-axSpA, which may suggest evidence of tissue repair.[5]

In PsA, approximately one in two patients treated with bimekizumab who were new to biologics and those with prior inadequate response or intolerance to tumour necrosis factor inhibitors (TNFi-IR) showed sustained achievement of minimal disease activity (MDA) over two years. Patients also achieved sustained remission up to two years as measured by the Disease Activity Index for Psoriatic Arthritis (DAPSA) remission or low disease activity (REM≤4; REM+LDA≤14) responses and DAPSA change from baseline.[4]

Highlights from the bimekizumab two-year data in axSpA presented at EULAR 2024:

- **ASAS40:** At Week 104, 49.2 percent of nr-axSpA patients (n=254) and 53.9 percent (n=332) of r-axSpA patients treated with bimekizumab achieved ASAS40.[1†]

- **Low Disease Activity:** At Week 104, 61.2 percent of nr-axSpA patients (n=254) and 63.4 percent of r-axSpA patients (n=332) treated with bimekizumab achieved low disease activity (ASDAS<2.1).[1‡]

- **Inactive Disease:** At Week 104, 31.6 percent of nr-axSpA patients (n=254) and 31.3 percent‡ of r-axSpA patients (n=332) achieved inactive disease (ASDAS <1.3).[1‡]

- **Radiographic Progression:** At Week 104, the majority of r-axSpA patients (157/190) treated with bimekizumab had no spinal radiographic progression as defined by modified Stoke Ankylosing Spondylitis Spinal Score (mSASSS) Change from Baseline (CfB) =0. The proportion of non-progressors was 85.3 percent (162/190), as defined by mSASSS CfB ≤0.5. The proportion of non-progressors was 92.1 percent (175/190), as defined by mSASSS CfB <2, which included 83.1 percent (69/83) of the patients who had existing structural damage (mSASSS ≥2) at baseline.[2]

- **Patient-Reported Outcomes:** Treatment with bimekizumab demonstrated consistently sustained improvements in spinal pain, morning stiffness and fatigue in patients with nr-axSpA and r-axSpA over two years, as reported by patients.[3]

- **Safety Profile:** The safety profile of bimekizumab in axSpA over two years was consistent with previous studies with no new safety signals observed.[1] To Week 104, 89.5 percent (514/574) of patients with axSpA had ≥1 treatment-emergent adverse event (TEAE) on bimekizumab.[1] The most frequent TEAEs by

exposure-adjusted incidence rate per 100 patient-years were SARS-CoV-2 infection (COVID-19; 13.2), nasopharyngitis (10.2), and upper respiratory tract infection (6.0).[1]

Highlights from the bimekizumab two-year data in PsA presented at EULAR 2024:

- **Minimal Disease Activity & Remission:** At Week 104, 52.4 percent of biologic-naïve PsA patients treated with bimekizumab (n=431) and 49.8 percent of biologic-naïve PsA patients who switched from placebo to bimekizumab (n=281) at Week 16 achieved MDA.[4†] In patients in the adalimumab reference arm who switched to bimekizumab at Week 52, the MDA response at Week 52 was sustained to Week 104. At Week 88, 46.1 percent of PsA TNFi-IR patients treated with bimekizumab (n=267) and 36.8 percent of PsA TNFi-IR patients who switched from placebo to bimekizumab (n=133) at Week 16 achieved MDA.[4 †] Trends were similar at Week 104/88 for achievement of DAPSA remission and low disease activity.[4]

Notes to editors:

[†]Non-Responder Imputation
[‡]Multiple Imputation

About Axial Spondyloarthritis
Axial Spondyloarthritis (axSpA), which includes both non-radiographic axSpA (nr-axSpA) and radiographic axSpA (r-axSpA), is a chronic, immune-mediated, inflammatory disease.[6] nr-axSpA is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.[6] axSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).[6] The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise but not with rest.[6] Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease and dactylitis.[6] The overall prevalence of axSpA is 0.3 percent to 1.4 percent of adults.[7,8] Approximately half of all patients with axSpA are patients with nr-axSpA.[6] axSpA onset usually occurs before the age of 45.[6] Approximately 10 to 40 percent of patients with nr-axSpA progress to r-axSpA over 2 to 10 years.[6]

About BE MOBILE 1 and BE MOBILE 2
BE MOBILE 1 and BE MOBILE 2 were two Phase 3 studies evaluating the efficacy and safety of bimekizumab in the treatment of nr-axSpA and r-axSpA, respectively.[9] The primary endpoint in both studies was Assessment of SpondyloArthritis International Society 40 percent (ASAS40) response at Week 16.[9] BE MOBILE 1 and BE MOBILE 2 comprised a 16-week double-blind treatment period followed by a 36-week maintenance period.[9] In BE MOBILE 1 and BE MOBILE 2, patients were randomized to bimekizumab (160 mg Q4W; N=128 for BE MOBILE 1 and N=221 for BE MOBILE 2) or to placebo (N=126 for BE MOBILE 1 and N=111 for BE MOBILE 2).[9] Patients initially randomized to placebo were switched to bimekizumab (160 mg Q4W) at Week 16.[9] At Week 52, those who completed either study were eligible to be enrolled into BE MOVING.[1,2] Of 254 nr-axSpA patients and 332 r-axSpA patients originally randomised to bimekizumab or placebo in BE MOBILE 1 and 2, respectively, 494 patients entered BE MOVING at Week 52.[1,2] By July 2023, 456 patients completed Week 104 (nr-axSpA n=189; r-axSpA n=267).[1,2]

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 and 6 percent to 41 percent of patients with psoriasis.[10] Symptoms include joint pain and stiffness, skin plaques, swollen toes

and fingers (dactylitis) and inflammation of the sites where tendons or ligaments insert into the bone (enthesitis).[11]

About BE OPTIMAL and BE COMPLETE

BE OPTIMAL and BE COMPLETE were two Phase 3 studies evaluating the efficacy and safety of bimekizumab in the treatment of psoriatic arthritis.[12,13] The primary endpoint in both studies was the proportion of patients reaching 50% or greater improvement in American College of Rheumatology criteria (ACR50) at Week 16 (non-responder imputation).[12,13] BE OPTIMAL (bDMARD-naïve) and BE COMPLETE (TNFi-IR) assessed subcutaneous bimekizumab 160 mg every four weeks (Q4W) in patients with PsA; both studies were placebo-controlled to Week 16, after which placebo patients switched to bimekizumab.[12,13] BE OPTIMAL included a reference arm (adalimumab 40 mg Q2W); adalimumab patients switched to bimekizumab at Week 52 with no washout between treatments. BE OPTIMAL Week 52 and BE COMPLETE Week 16 completers were eligible for BE VITAL open-label extension.[4] From BE OPTIMAL 83.3 percent of patients (n=710/852) and from BE COMPLETE 82.5 percent (n=330/400) completed Week 104 and Week 88, respectively.[4] Outcomes are reported to Week 88 for BE COMPLETE because 18 (4.5%) had not yet attended their Week 100 visit.[4]

About bimekizumab

Bimekizumab 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.[14]

The therapeutic indications 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.[15]
- 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).[15]
- 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.[15]
- 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.[15]

BIMZELX® ▼ (bimekizumab) EU/EEA* Important Safety Information[15]

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).

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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: April 2024. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

*EU/EEA means European Union/European Economic Area

▼ *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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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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References

1. Baraliakos X, Deodhar A, van der Heijde D, et al. Long-term sustained efficacy and safety of bimekizumab across the full spectrum of axial spondyloarthritis: 2-year results from two Phase 3 studies. Abstract at EULAR 2024, Vienna, Austria.
2. Baraliakos X, Ramiro S, Maksymowych WP, et al. Minimal spinal radiographic progression in patients with radiographic axial spondyloarthirits over two years of bimekizumab treatment: results from a Phase 3 open-label extension study. Late-breaking presentation at EULAR 2024, Vienna, Austria.
3. Marzo-Ortega H, Mease P, Dougados M, et al. Sustained improvements with bimekizumab in patient-reported symptoms of axial spondyloarthritis: 2-year results from two phase 3 studies. Abstract at EULAR 2024, Vienna, Austria.
4. Coates L, Kristensen L, Ogdie A, et al. Bimekizumab-treated patients with active psoriatic arthritis showed sustained achievement of minimal disease activity and remission: up to 2-year results from two phase 3 studies. Abstract at EULAR 2024, Vienna, Austria.
5. Maksymowych W, Ramiro S, Poddubnyy D, et al. Impact of bimekizumab on MRI inflammatory and structural lesions in the sacroiliac joints of patients with axial spondyloarthritis: 52-week results and post hoc analyses from the BE MOBILE 1 and 2 phase 3 studies. Abstract at EULAR 2024, Vienna, Austria.
6. Deodhar A. Understanding Axial Spondyloarthritis: A Primer for Managed Care. Am J Manag Care. 2019;25:S319-S330.
7. Reveille JD, Witter JP, Weisman MH. Prevalence of axial spondyloarthritis in the United States: estimates from a cross-sectional survey. Arthritis Care Res (Hoboken). 2012;64:905-10.
8. 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.
9. 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;83:199–213.
10. Ogdie A, Weiss P. The Epidemiology of Psoriatic Arthritis. Rheum Dis Clin North Am. 2015;41:545-68
11. 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.
12. 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.
13. 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. doi:10.1136/rmdopen-2023-003855
14. Glatt S, Helmer E, Haier B, et al. First-in-human randomized study of bimekizumab, a humanized monoclonal antibody and selective dual inhibitor of IL-17A and IL-17F, in mild psoriasis. Br J Clin Pharmacol. 2017;83:991–1001.
15. BIMZELX® (bimekizumab) EU SmPC. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Accessed: June 2024.