



Bimekizumab Demonstrated Sustained Clinical Responses to Week 52 in Phase 3 Studies in Psoriatic Arthritis, Non-Radiographic Axial Spondyloarthritis and Ankylosing Spondylitis

- New late-breaking 52-week data from Phase 3 bimekizumab investigational studies in psoriatic arthritis and across the spectrum of axial spondyloarthritis, including non-radiographic axial spondyloarthritis and ankylosing spondylitis, presented at ACR Convergence 2022
- In BE OPTIMAL, clinical joint and skin clearance responses in psoriatic arthritis were sustained to week 52 with bimekizumab treatment
- In BE MOBILE 1 and BE MOBILE 2, treatment with bimekizumab resulted in sustained clinical responses to week 52, including suppression of inflammation and improvements in function and quality of life across the full spectrum of axial spondyloarthritis
- The adverse event profile of bimekizumab to week 52 in psoriatic arthritis, non-radiographic axial spondyloarthritis and ankylosing spondylitis is consistent with previous observations with no new safety signals

Brussels (Belgium), 10th November 2022 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced the first presentation of long-term, 52-week data from three Phase 3 studies evaluating the efficacy and safety of bimekizumab in adults with active psoriatic arthritis (PsA) who were biologic-naïve (BE OPTIMAL), in adults with active non-radiographic axial spondyloarthritis (nr-axSpA; BE MOBILE 1), and in adults with active ankylosing spondylitis, also known as radiographic axSpA (AS; BE MOBILE 2).^{1,2} These late-breaking data are being presented at ACR Convergence 2022 in Philadelphia, November 10–14, 2022.^{1,2} The safety and efficacy of bimekizumab in PsA, nr-axSpA and AS have not been established, and it is not approved for use in PsA, nr-axSpA or AS by any regulatory authority worldwide.

Data from BE OPTIMAL showed that clinical joint and skin clearance responses in patients with active psoriatic arthritis were sustained to week 52 with bimekizumab treatment.¹ In addition, data from BE MOBILE 1 and BE MOBILE 2, showed that across the full spectrum of axSpA, encompassing nr-axSpA and AS, treatment with bimekizumab resulted in sustained improvement in the signs and symptoms of disease, including suppression of inflammation and improvements in physical function and quality of life, to week 52.² These outcomes were consistent across both TNF-inhibitor (TNFi) naïve and TNFi-inadequate responder populations.² In all three studies, the adverse event profile of bimekizumab was consistent with data seen in previous studies with no new observed signals.^{1,2}

“The 52-week data shared today demonstrate the high thresholds of disease control that were achieved by the majority of patients across these three studies. The results build on the previously announced 24-week data and show that bimekizumab sustained a clinically meaningful impact for patients through one year,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

GL-N-BK-axSpA-2200109
Date of preparation: November 2022



BE OPTIMAL (PsA): Phase 3 Study Results (52 weeks)¹

In BE OPTIMAL, patients were randomized (3:2:1) to bimekizumab (160 mg every four weeks [Q4W]; N=431), placebo (N=281) or the active reference arm (adalimumab 40 mg every two weeks [Q2W]; N=140). Patients initially randomized to placebo were switched to bimekizumab at week 16. A total of 89.3 percent of randomized patients completed week 52. Key 52-week results from the BE OPTIMAL study are presented below and build upon previously announced [16- and 24-week results](#).

- **ACR50:** At week 52, 54.5 percent of patients continuously treated with bimekizumab, 53.0 percent of patients who switched from placebo to bimekizumab at week 16, and 50.0 percent of patients in the reference arm (adalimumab) achieved ACR50.
- **Complete Skin Clearance (PASI 100):** At week 52, in patients with baseline psoriasis ≥ 3 percent body surface area^Y, 60.8 percent of patients continuously treated with bimekizumab, 65.0 percent of patients who switched from placebo to bimekizumab at week 16, and 48.5 percent of patients in the reference arm (adalimumab) achieved PASI 100.
- **Minimal Disease Activity (MDA):** At week 52, 55.0 percent of patients continuously treated with bimekizumab, 53.7 percent of patients who switched from placebo to bimekizumab at week 16, and 52.9 percent of patients in the reference arm (adalimumab) achieved MDA.

“The long-term bimekizumab data presented at ACR Convergence 2022 in patients with psoriatic arthritis show clinically meaningful improvements in joint and skin outcomes through to one year. In BE OPTIMAL, at week 52, over six out of 10 patients treated with bimekizumab achieved complete skin clearance and one in two patients achieved minimal disease activity. Long-term data such as these are important since they may help to inform clinical decision making of the future,” said Christopher Ritchlin MD, MPH, Professor of Medicine and faculty member in the Allergy, Immunology & Rheumatology Division, University of Rochester Medical School, Rochester, New York, U.S.

Over 52 weeks, 79.1 percent of patients treated with bimekizumab had \geq one treatment emergent adverse event (TEAE) and 80.7 percent on adalimumab.¹ The three most frequent TEAEs with bimekizumab treatment were nasopharyngitis (12.0 percent), upper respiratory tract infection (7.1 percent) and urinary tract infection (6.1 percent).¹

BE MOBILE 1 and BE MOBILE 2 (axSpA): Phase 3 Study Results (52 weeks)²

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). Patients initially randomized to placebo were switched to bimekizumab at week 16. A total of 86.6 percent randomized patients with nr-axSpA and 89.8 percent with AS completed week 52. Key 52-week results from the BE MOBILE 1 and BE MOBILE 2 studies are presented below and build upon previously announced [16- and 24-week results](#):

- **ASAS40:** At week 52, 60.9 percent of nr-axSpA patients and 58.4 percent of AS patients continuously treated with bimekizumab achieved ASAS40, with consistent outcomes across both TNFi-naïve and TNFi-inadequate responder populations.
- **Low Disease Activity and Remission:** At week 52, 61.6 percent of nr-axSpA patients and 57.1 percent of AS patients continuously treated with bimekizumab achieved low disease activity (ASDAS $<$ 2.1); at week 52, inactive disease or clinical remission (ASDAS $<$ 1.3) was achieved by 25.2 percent of nr-axSpA patients and 23.4 percent of AS patients continuously treated with bimekizumab.

GL-N-BK-axSpA-2200109
Date of preparation: November 2022



- **Objective Inflammation:** The reductions from baseline in objective signs of inflammation (Magnetic Resonance Imaging [MRI], hs-C-Reactive Protein [hs-CRP]) for patients with nr-axSpA and AS were sustained through week 52.

In addition, improvements in function as measured by the Bath Ankylosing Spondylitis Functional Index (BASFI) and quality of life, as measured by Ankylosing Spondylitis Quality of Life (ASQoL), were sustained through week 52.

“Results presented today from BE MOBILE 1 and BE MOBILE 2 demonstrate that treatment with bimekizumab provided consistent and sustained improvements to one year in key signs and symptoms across the full spectrum of axial spondyloarthritis, with similar outcomes regardless of previous treatment with TNF inhibitors. These positive results are the first Phase 3 data evaluating a dual IL-17A and IL-17F inhibitor, bimekizumab, in the long-term treatment of patients living with non-radiographic axial spondyloarthritis and ankylosing spondylitis,” said Professor Xenofon Baraliakos, Rheumazentrum Ruhrgebiet Herne, Ruhr-University Bochum, Germany.

Over 52 weeks, 75.0 percent of nr-axSpA patients treated with bimekizumab and 75.5 percent of AS patients had ≥ 1 TEAE.² The most frequent TEAEs were nasopharyngitis (nr-axSpA 12.3 percent; AS 9.1 percent), upper respiratory tract infection (nr-axSpA 9.4 percent; AS 6.4 percent) and oral candidiasis (nr-axSpA 7.4 percent; AS 6.1 percent); few COVID-19 infections were reported (nr-axSpA: 7.0 percent; AS; 2.1 percent).² The incidence of serious TEAEs was low (nr-axSpA 4.4 percent; AS 7.1 percent).²

Notes to editors:

The primary endpoint in the BE OPTIMAL study was ACR50 at week 16 with ranked secondary endpoints including PASI90 and MDA at week 16; the primary endpoint in the BE MOBILE 1 and BE MOBILE 2 studies was ASAS40 at week 16.

[‡]In patients with psoriasis affecting $\geq 3\%$ body surface area at baseline; n=217 for patients continuing treatment with bimekizumab; n=140 for patients switching from placebo to bimekizumab at week 16 and n=68 for patients continuing treatment with adalimumab

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.³ 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).⁴

About Axial Spondyloarthritis

Axial Spondyloarthritis (axSpA), which includes both non-radiographic axSpA and ankylosing spondylitis (AS), also known as radiographic axSpA (r-axSpA), is a chronic, immune-mediated, inflammatory disease.⁵ nr-axSpA is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.⁵ AxSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).⁵ The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise, but not with rest.⁵ Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease and dactylitis.⁵ The overall prevalence of axSpA is 0.3 percent to 1.2 percent of adults.^{6,7} Approximately half of all patients with axSpA are patients with



nr-axSpA.⁵ AxSpA onset usually occurs before the age of 45.⁵ Approximately 10 to 40 percent of patients with nr-axSpA progress to ankylosing spondylitis over 2 to 10 years.⁵

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.^{8,9} In August 2021, bimekizumab was approved in the European Union (EU)/European Economic Area (EEA) and in Great Britain, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.^{9,10} The label information may differ in other countries. Please check local prescribing information. In the U.S., the efficacy and safety of bimekizumab have not been established for any indication and it is not approved by the U.S. Food and Drug Administration (FDA).

BIMZELX® ▼ (bimekizumab) EU/EEA Important Safety Information in Psoriasis⁹

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%) (most frequently nasopharyngitis) and oral candidiasis (7.3%). Common adverse reactions ($\geq 1/100$ to $< 1/10$) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, headache, dermatitis and eczema, acne, injection site reactions and 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 administered 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. Prior to initiating treatment with bimekizumab, patients should be evaluated for tuberculosis (TB) infection. Bimekizumab should not be given in patients with active TB and 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. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

EU summary of product characteristics date of revision: May 2022.

Last accessed: November 2022.

GL-N-BK-axSpA-2200109
Date of preparation: November 2022



▼ *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

Eimear O'Brien
T +32.2.559.92.71
email eimear.obrien@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 8,600 people in approximately 40 countries, the company generated revenue of €5.8 billion in 2021. 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: the global spread and impact of COVID-19, 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

GL-N-BK-axSpA-2200109
Date of preparation: November 2022



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 and it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated otherwise. UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. 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. Ritchlin C, Coates L, McInnes I, et al. Bimekizumab treatment in biologic DMARD-naïve patients with active psoriatic arthritis: 52-week efficacy and safety results from a Phase 3, randomized, placebo-controlled, active reference study. #L02 Presented at ACR Convergence 2022. <https://acrabstracts.org/abstract/bimekizumab-treatment-in-biologic-dmard-naive-patients-with-active-psoriatic-arthritis-52-week-efficacy-and-safety-results-from-a-phase-3-randomized-placebo-controlled-active-reference-study/>
2. Baraliakos X, Deodhar A, van der Heijde D, et al. Bimekizumab maintains improvements in efficacy endpoints and has a consistent safety profile through 52 weeks in patients with non-radiographic axial spondyloarthritis and ankylosing spondylitis: results from two parallel Phase 3 studies. #L14 Presented at ACR Convergence 2022. <https://acrabstracts.org/abstract/bimekizumab-maintains-improvements-in-efficacy-endpoints-and-has-a-consistent-safety-profile-through-52-weeks-in-patients-with-non-radiographic-axial-spondyloarthritis-and-ankylosing-spondylitis-resu/>
3. Ogdie A, Weiss P. The Epidemiology of Psoriatic Arthritis. *Rheum Dis Clin North Am.* 2015; 41(4): 545–568.
4. Mease PJ, Armstrong AW. Managing patients with psoriatic disease: the diagnosis and pharmacologic treatment of psoriatic arthritis in patients with psoriasis. *Drugs.* 2014; 74:423-441.
5. Deodhar A. Understanding Axial Spondyloarthritis: A Primer for Managed Care. *Am J Manag Care.* 2019;25:S319-S330.
6. 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):905-910.
7. 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;21;16:392.
8. 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(5):991-1001.
9. BIMZELX® (bimekizumab) EU Summary of Product Characteristics. https://www.ema.europa.eu/en/documents/product-information/bimzeli-x-epar-product-information_en.pdf. Last accessed: November 2022.
10. BIMZELX® (bimekizumab) GB Summary of Product Characteristics. <https://www.medicines.org.uk/emc/product/12834>; <https://www.medicines.org.uk/emc/product/12833>. Last accessed: November 2022.