UCB News

New Long-Term Data on Bimekizumab in Psoriatic Arthritis and Axial Spondyloarthritis Presented at EULAR 2023

- In patients with psoriatic arthritis with prior inadequate response to tumour necrosis factor inhibitors, bimekizumab demonstrated sustained joint and skin clearance responses to week 52
- Across the spectrum of axial spondyloarthritis, bimekizumab demonstrated sustained reduction of inflammatory lesions of the sacroiliac joints and spine, as well as sustained improvements in the main peripheral manifestations of disease, to week 52

Brussels (Belgium), 31st May 2023 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced new long-term 52-week data from three Phase 3 studies – BE COMPLETE with its long-term extension study, BE MOBILE 1 and BE MOBILE 2 – evaluating the efficacy and safety profile of bimekizumab, an inhibitor of IL-17F in addition to IL-17A, in adults with active psoriatic arthritis (PsA), active non-radiographic axial spondyloarthritis (nr-axSpA) and active ankylosing spondylitis (AS), also known as radiographic axSpA (r-axSpA), respectively.[1,2,3] These results from the bimekizumab phase 3 program in PsA and axSpA are being presented at the European Congress of Rheumatology, EULAR 2023, in Milan, Italy, May 31–June 3. The safety and efficacy of bimekizumab in PsA, nr-axSpA and r-axSpA have not been established, and it is not approved for use in PsA, nr-axSpA or AS by any regulatory authority worldwide.

"Psoriatic arthritis and axial spondyloarthritis are chronic and progressive inflammatory diseases requiring long-term management. The new long-term bimekizumab data presented at EULAR 2023 showed sustained clinical responses across multiple disease manifestations and patient populations up to one year. These results reinforce our belief in bimekizumab as a potential new future treatment for patients living with psoriatic arthritis and axial spondyloarthritis," said Emmanuel Caeymaex, Executive Vice President, Immunology and U.S. Solutions, UCB.

Bimekizumab 52-week PsA data: patients with prior inadequate response to tumour necrosis factor inhibitors (TNFi-IR)

Key 52-week results from the BE COMPLETE open-label extension study (BE VITAL) are shared below and build on the previously announced 16-week results from the BE COMPLETE study and 52-week results from the BE OPTIMAL study.[1]

"The long-term data from BE COMPLETE showed that over six out of 10 patients continuously treated with bimekizumab achieved complete skin clearance and almost one in two had minimal disease activity at week 52. These results complement the previously reported 52-week results from the BE OPTIMAL study and highlight the consistent and sustained response seen with bimekizumab in both biologic-naïve and TNF inhibitor-experienced patients with psoriatic arthritis," said Professor Iain McInnes, University of Glasgow, College of Medicinal Veterinary and Life Sciences, Glasgow, Scotland.

GL-N-BK-axSpA-2300016
Date of preparation: May 2023

- **American College of Rheumatology (ACR) 50:** At week 52, 51.7 percent of psoriatic arthritis patients (TNFi-IR) continuously treated with bimekizumab (160 mg every four weeks [Q4W]; n=267), and 40.6 percent of patients who switched from placebo to bimekizumab at week 16 (n=133) achieved ACR50.[1±]
- **Complete Skin Clearance (PASI100):** At week 52, in patients with baseline psoriasis ≥3 percent body surface area, 65.9 percent of patients continuously treated with bimekizumab (n=176) and 60.2 percent of patients who switched from placebo to bimekizumab at week 16 (n=88) achieved complete skin clearance (PASI100).[1±]
- **Minimal Disease Activity (MDA):** At week 52, 47.2 percent (n=126/267) of patients continuously treated with bimekizumab and 33.1 percent (n=44/133) of patients who switched from placebo to bimekizumab achieved MDA.[1±]

Over 52 weeks, 62.6 percent (n=243/388) of patients treated with bimekizumab had ≥1 treatment emergent adverse event (TEAE) and 5.9 percent (n=23/388) reported a serious TEAE.[1] *Candida* infections were reported by 6.4 percent (n=25/388) of patients receiving bimekizumab with all cases reported as mild or moderate and none reported as systemic.[1]

Bimekizumab 52-week axSpA data: inflammation of the sacroiliac joints and spine and peripheral manifestations

Key 52-week results from the phase 3 BE MOBILE 1 and BE MOBILE 2 studies evaluating the effect of bimekizumab on inflammatory lesions of the sacroiliac joints (SIJ) and spine as measured objectively by magnetic resonance imaging (MRI), and on the main peripheral manifestations of axSpA are shared below and build on previously announced 16-week and 52-week results from BE MOBILE 1 and BE MOBILE 2.[2,3]

"Treatment with bimekizumab versus placebo reduced inflammation of the spine and sacroiliac joints as detected by magnetic resonance imaging. In the two studies, approximately one in two patients with MRI inflammation at baseline achieved MRI remission at week 16, which was sustained out to week 52," said Xenofon Baraliakos, Professor of Internal Medicine and Rheumatology, Ruhr-University Bochum, Bochum, Germany.

- **Inflammation SIJ:** At week 52, in the BE MOBILE 1 imaging sub-study, 80.0 percent (n=32/40) of patients with inflammation at baseline receiving continuous bimekizumab and 57.1 percent (n=20/35) who switched from placebo to bimekizumab at week 16 achieved remission in inflammatory lesions of the SIJs (Spondyloarthritis Research Consortium of Canada [SPARCC SIJ<2]); in BE MOBILE 2, 75.7 percent (n=28/37) receiving bimekizumab and 66.7 percent (n=12/18) who switched from placebo to bimekizumab at week 16 achieved remission in inflammatory lesions of the SIJ.[2¥]

- **Inflammation Spine:** At week 52, in the BE MOBILE 1 imaging sub-study, 40.0 percent (n=6/15) of patients with inflammation at baseline receiving continuous bimekizumab and 27.3 percent (n=3/11) who switched from placebo to bimekizumab at week 16 achieved remission (Berlin Spine≤2); in BE MOBILE 2, 76.7 percent (n=23/30) receiving continuous bimekizumab and 62.5 percent (n=10/16) who switched from placebo to bimekizumab at week 16 achieved remission.[2¥]

- **Enthesitis:** At week 52, in BE MOBILE 1, 54.3 percent of patients receiving continuous bimekizumab (n=94) and 44.6 percent who switched from placebo to bimekizumab (n=92) at week 16 achieved resolution of enthesitis (Maastricht Ankylosing Spondylitis Enthesitis=0); in BE MOBILE 2, 50.8 percent

GL-N-BK-axSpA-2300016
Date of preparation: May 2023

receiving continuous bimekizumab (n=132) and 46.3 percent who switched from placebo to bimekizumab at week 16 (n=67) achieved resolution of enthesitis.[3±]

- **Peripheral arthritis:** At week 52, in BE MOBILE 1, 62.2 percent of patients receiving continuous bimekizumab (n=45) and 65.1 percent who switched from placebo to bimekizumab at week 16 (n=43) achieved resolution (Swollen Joint Count=0); in BE MOBILE 2, 72.7 percent receiving continuous bimekizumab (n=44) and 81.8 percent who switched from placebo to bimekizumab at week 16 (n=22) achieved resolution (Swollen Joint Count=0).[3±]

In addition, in the largest pool of bimekizumab phase 2b and phase 3 data available, the exposure-adjusted incidence rate of uveitis in patients with axSpA treated with bimekizumab (160 mg Q4W) remains low at 1.2/100 patient-years. In this pooled data, the total bimekizumab exposure was 2,034.4 patient years (N=848) and 15.3 percent of patients (n=130) had a history of uveitis. All uveitis TEAEs reported were mild to moderate and one event led to discontinuation.[4]

Notes to editors:

±–Non-responder imputation
¥ ⁻ Observed Case

About BE COMPLETE
BE COMPLETE was a 16-week randomized, double-blind, placebo-controlled study in which patients with active psoriatic arthritis and prior inadequate response to tumor necrosis factor inhibitors (TNFi-IR) were randomized (2:1) to bimekizumab (160 mg every four weeks [Q4W]; N=267) or placebo (N=133).[1] Week 16 completers were eligible to enter the open-label extension up to one year.[1] Patients initially randomized to placebo were switched to bimekizumab at week 16 and received 36 weeks' bimekizumab treatment up to week 52.[1] A total of 86.8 percent (n=347) of randomized patients completed week 52.[1] The primary endpoint in the BE COMPLETE study was ACR50 at week 16 with ranked secondary endpoints including PASI90 at week 16 and minimal disease activity (MDA) at week 16, with other endpoints including complete skin clearance (PASI100) at week 16.[5]

About BE MOBILE 1 and BE MOBILE 2 [2,3]
The phase 3 studies BE MOBILE 1 and BE MOBILE 2 comprised a 16-week double-blind treatment period followed by a 36-week maintenance period. 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 (160 mg Q4W) at week 16. The primary endpoint in the BE MOBILE 1 and BE MOBILE 2 studies was ASAS40 at week 16.[6]

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.[7,8] In August 2021, bimekizumab was first 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.[8,9] The label information may differ in other countries. Please check local prescribing information where approved.

GL-N-BK-axSpA-2300016
Date of preparation: May 2023

UCB News

BIMZELX® ▼ (bimekizumab) EU/EEA Important Safety Information in Psoriasis[8]
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 (≥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: May 2023.

▼ *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

GL-N-BK-axSpA-2300016
Date of preparation: May 2023

Inspired by patients.
Driven by science.

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 8,700 people in approximately 40 countries, the company generated revenue of €5.5 billion in 2022. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

Forward looking statements
This press release may contain forward-looking statements including, without limitation, statements containing the words "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, will progress to product approval or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products, which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB's efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

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.

GL-N-BK-axSpA-2300016
Date of preparation: May 2023

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. Coates LC, Landewé R, McInnes IB, et al. Sustained efficacy and safety of bimekizumab in patients with active psoriatic arthritis and prior inadequate response to tumour necrosis factor inhibitors: Results from the phase 3 BE COMPLETE study and its open-label extension up to 1 year. Abstract #POS0231 presented at EULAR 2023, Milan, Italy.
2. Baraliakos X, Navarro-Compan V, Poddubnyy D, et al. Bimekizumab reduced MRI inflammatory lesions in patients with axial spondyloarthritis: Week 52 results from the BE MOBILE 1 and BE MOBILE 2 phase 3 studies. Abstract #POS0246 presented at EULAR 2023, Milan, Italy.
3. Ramiro S, Poddubnyy D, Mease PJ, et al. Resolution of enthesitis and peripheral arthritis with bimekizumab in patients with axial spondyloarthritis: Week 52 results from the BE MOBILE 1 and BE MOBILE 2 phase 3 studies. Abstract #POS0247 presented at EULAR 2023, Milan, Italy.
4. Brown M, van Gaalen FA, van der Horst-Bruinsma IE, et al. Low uveitis rates in patients with axial spondyloarthritis treated with bimekizumab: Pooled results from phase 2b/3 trials. Abstract #POS0668 presented at EULAR 2023, Milan, Italy.
5. 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.
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. Published Online First: January 2023. doi:10.1136/ard-2022-223595. Last accessed: May 2023.
7. 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.
8. BIMZELX® (bimekizumab) EU SmPC. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Accessed on May 2023.
9. BIMZELX® (bimekizumab) GB SmPC. https://www.medicines.org.uk/emc/product/12834. https://www.medicines.org.uk/emc/product/12833 Accessed on May 2023.

GL-N-BK-axSpA-2300016
Date of preparation: May 2023