UCB News

First Presentations of Phase 3 Data for Bimekizumab Across the Full Spectrum of Axial Spondyloarthritis to be Shared at EULAR 2022

- New data from BE MOBILE 1 and BE MOBILE 2 show that bimekizumab achieved consistent improvements versus placebo in signs and symptoms across the full spectrum of axial spondyloarthritis (axSpA), including non-radiographic axSpA (nr-axSpA) and ankylosing spondylitis (AS)

- Treatment with bimekizumab delivered clinically meaningful efficacy outcomes in nr-axSpA and AS, as measured by the proportion of patients achieving the primary endpoint (ASAS40) and all ranked secondary endpoints versus placebo

Brussels (Belgium), 23 May 2022 – 8:30 (CEST) – UCB, a global pharmaceutical company, today announced new 24-week data from two Phase 3 studies, BE MOBILE 1 and BE MOBILE 2, evaluating bimekizumab in the treatment of active non-radiographic axial spondyloarthritis (nr-axSpA) and active ankylosing spondylitis (AS).[1,2] Both studies met their primary and all ranked secondary endpoints at week 16, with statistical significance, demonstrating improvements versus placebo in the signs and symptoms of disease across the full spectrum of axSpA with consistent outcomes for patients with nr-axSpA and patients with AS.[1,2] The safety profile of bimekizumab in both studies was consistent with safety data seen in previous studies with no new observed safety signals.[1,2]

UCB also announced today new post-hoc analyses from the open-label extension of the Phase 2b BE AGILE study, in which bimekizumab showed maintenance of clinical responses over three years in patients with active AS.[3] Data from all three studies will be presented at the European Congress of Rheumatology, EULAR 2022, in Copenhagen, Denmark, June 1–4. Bimekizumab is not approved for use in nr-axSpA or AS by any regulatory authority worldwide. The safety and efficacy of bimekizumab in nr-axSpA and AS have not been established.

"We are pleased to share the first detailed data from our Phase 3 clinical program of bimekizumab in non-radiographic axSpA and ankylosing spondylitis, which showcase the clinical potential of bimekizumab to improve patient outcomes across the full spectrum of this debilitating disease," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. "People with axSpA often live with the condition for many years before diagnosis, with limited options available today to treat non-radiographic axSpA. We are driven to bring differentiated solutions that address unmet needs, and these results are an important step in our mission, setting the foundation for future regulatory discussions."

BE MOBILE 1 and BE MOBILE 2: Phase 3 Study Results (24 weeks)[1,2]

In BE MOBILE 1 and BE MOBILE 2, patients treated with bimekizumab (160 mg every 4 weeks [Q4W]) achieved statistically significant and clinically meaningful improvements in the signs and symptoms of axSpA, as defined by the primary endpoint measure of Assessment of SpondyloArthritis International Society 40

(ASAS40) at week 16 compared to placebo.[1,2] Response rates increased to week 24 and a rapid achievement of ASAS40 response was seen for patients switching from placebo to bimekizumab at week 16.[1,2]

- **BE MOBILE 1 (nr-axSpA):** At week 16, 47.7 percent (n=61/128) of bimekizumab-treated patients achieved ASAS40 versus 21.4 percent (n=27/126) with placebo (p<0.001).[1]
- **BE MOBILE 2 (AS):** At week 16, 44.8 percent (n=99/221) of bimekizumab-treated patients achieved ASAS40 versus 22.5 percent (n=25/111) with placebo (p<0.001).[2]

"Today's findings from the BE MOBILE 1 and BE MOBILE 2 studies provide clear evidence supporting the potential of bimekizumab in both nr-axSpA and AS, and highlight the meaningful clinical outcomes that can be achieved by targeting IL-17F in addition to IL-17A. Patients with nr-axSpA and AS have a similar burden of disease and a treatment that could potentially show consistent outcomes across the full spectrum of disease is encouraging," said Professor Atul Deodhar, MD, MRCP, Professor of Medicine, Division of Arthritis and Rheumatic Diseases, Oregon Health & Science University, Portland, OR, U.S.

In both studies, at week 16, patients treated with bimekizumab achieved statistically significant improvements in all ranked secondary endpoints compared with placebo, including ASAS partial remission (ASAS-PR), disease activity as measured by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), physical function as measured by the Bath Ankylosing Spondylitis Functional Index (BASFI), and quality of life as measured by Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire.[1,2]

BE MOBILE 1 (nr-axSpA):

- At week 16, 25.8 percent (n=33/128) of bimekizumab-treated patients achieved ASAS-PR versus 7.1 percent (n=9/126) of patients with placebo (p<0.001).[1]
- At week 16, mean change from baseline in BASDAI (-3.1 bimekizumab versus -1.5 placebo, p<0.001).[1]
- At week 16, mean change from baseline in BASFI (-2.5 bimekizumab versus -1.0 placebo, p<0.001).[1]
- At week 16, mean change from baseline in ASQoL (-5.2 bimekizumab versus -2.5 placebo, p<0.001).[1]

BE MOBILE 2 (AS):

- At week 16, 24.0 percent (n=53/221) of bimekizumab-treated patients achieved ASAS-PR versus 7.2 percent (n=8/111) of patients with placebo (p<0.001).[2]
- At week 16, mean change from baseline in BASDAI (-2.9 bimekizumab versus -1.9 placebo, p<0.001).[2]
- At week 16, mean change from baseline in BASFI (-2.2 bimekizumab versus -1.1 placebo, p<0.001).[2]
- At week 16, mean change from baseline in ASQoL (-4.9 bimekizumab versus -3.2 placebo, p<0.001).[2]

Other efficacy outcomes in BE MOBILE 1 and BE MOBILE 2 included changes in Ankylosing Spondylitis Disease Activity Score (ASDAS) states, and changes in inflammation in the sacroiliac joints and spine as measured by Magnetic Resonance Imaging (MRI).[1,2] At the start of both studies, almost all patients (>97 percent) had high or very high disease activity.[1,2] At week 24, in both studies, approximately half of the patients treated with bimekizumab from the start of each study achieved ASDAS low disease activity defined as ASDAS<2.1.[1,2] Treatment with bimekizumab also resulted in substantial reductions in inflammation in the sacroiliac joints and spine for both AS and nr-axSpA patients at week 16.[1,2]

Professor Désirée van der Heijde, Professor of Rheumatology, Leiden University Medical Center, Leiden, the Netherlands, said, "Patients with axSpA live with a range of debilitating symptoms including chronic back pain and difficulties performing everyday tasks. These interim results from the BE MOBILE 1 and BE MOBILE 2 studies are encouraging, showing that treatment with bimekizumab versus placebo improved signs and

symptoms, reduced disease activity and inflammation, and improved physical function. We look forward to the 52-week results from these studies expected later this year."

In BE MOBILE 1, the most common treatment emergent adverse events (TEAEs) over 16 weeks with bimekizumab were nasopharyngitis (9.4 percent), upper respiratory tract infection (7.0 percent) and oral candidiasis (3.1 percent).[1] In BE MOBILE 2, the most common TEAEs over 16 weeks were nasopharyngitis (7.7 percent), headache (4.1 percent) and oral candidiasis (4.1 percent).[2] Up to 16 weeks, the incidence of serious adverse events was low with bimekizumab in both studies (0 percent in BE MOBILE 1 and 1.8 percent in BE MOBILE 2).[1,2] In BE MOBILE 1, no cases of inflammatory bowel disease (IBD) were reported with patients taking bimekizumab.[1] In BE MOBILE 2, two IBD cases (0.9 percent) occurred in patients treated with bimekizumab.[2]

BE AGILE Phase 2b Open-Label Extension: 3 Year Study Results[3]

Post-hoc analyses of the Phase 2b BE AGILE study and its open-label extension showed that treatment with bimekizumab (160 mg Q4W) provided maintenance of clinical responses over three years (156 weeks) in patients with active AS who initially responded at week 12, and irrespective of the initial dosing regimen (160 mg Q4W, [N=60] or 320 mg Q4W, [N=61]).[3] At week 12, 40.3 percent of patients had achieved low disease activity (ASDAS<2.1), and 89.2 percent of these patients maintained this low level of disease activity at week 156.[3] Efficacy measured by ASAS40 response was also sustained over three years, with 47.1 percent of patients having achieved ASAS40 at week 12, 64.9 percent at week 48 and 71.9 percent at week 156.[3]

Notes to editors :

About BE MOBILE 1

BE MOBILE 1 is a randomized, multicenter, double-blind, placebo-controlled, parallel-group, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in the treatment of adult patients with active nr-axSpA.[1] The study is ongoing with 24-week results presented above. For additional details on the study, visit BE MOBILE 1 on clinicaltrials.gov.[4]

About BE MOBILE 2

BE MOBILE 2 is a randomized, multicenter, double-blind, placebo-controlled, parallel-group, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in the treatment of adult patients with active AS.[2] The study is ongoing with 24-week results presented above. For additional details on the study, visit BE MOBILE 2 on clinicaltrials.gov.[5]

About BE AGILE and the open-label extension study (BE AGILE 2)

BE AGILE was a multicenter, Phase 2b, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study to evaluate the efficacy and safety of bimekizumab in patients with active ankylosing spondylitis (AS).[6] BE AGILE 2 is a multicenter, open-label extension study to evaluate the long term safety and efficacy of bimekizumab in patients with active AS. For additional details, visit BE AGILE 2 on clinicaltrials.gov.[7]

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.[8] nr-axSpA is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.[8] AxSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).[8] The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise, but not with rest.[8] Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease and dactylitis.[8] The overall prevalence of

axSpA is 0.3 percent to 1.3 percent of adults.[9,10] Approximately half of all patients with axSpA are patients with nr-axSpA.[8] AxSpA onset usually occurs before the age of 45.[8] Approximately 10 to 40 percent of patients with nr-axSpA progress to ankylosing spondylitis over 2 to 10 years.[8]

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.[11,14] Bimekizumab is in Phase 3 clinical development for the treatment of active axSpA with 24-week interim analysis results from the BE MOBILE 1 (nr-axSpA) and BE MOBILE 2 (AS) studies to be presented at EULAR 2022.[1,2] In addition, bimekizumab is in Phase 3 clinical development for the treatment of active psoriatic arthritis with 24-week interim analysis from the BE OPTIMAL study and 16-week analysis from the BE COMPLETE study to be presented at EULAR 2022.[12,13]

About BIMZELX® ▼ (bimekizumab) in the European Union /European Economic Area
In the European Union (EU)/European Economic Area (EEA) BIMZELX® is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[14]

BIMZELX® ▼ (bimekizumab) EU/EEA Important Safety Information in Psoriasis
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, 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.

GL-N-BK-axSpA-2200010
Date of preparation: May 2022

UCB News

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 March 2022.

Last accessed: May 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

GL-N-BK-axSpA-2200010
Date of preparation: May 2022

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 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. Deodhar A, van der Heijde D, Gensler LS et al. Bimekizumab in patients with active non-radiographic axial spondyloarthritis: 24-week efficacy and safety from BE MOBILE 1, a phase 3, multicentre, randomised, placebo-controlled study. To be presented at EULAR 2022 in Copenhagen, Denmark, June 1-4.
2. van der Heijde D, Baraliakos X, Dougados M et al. Bimekizumab in patients with active ankylosing spondylitis: 24-week efficacy and safety from BE MOBILE 2, a phase 3, multicentre, randomised, placebo-controlled study. To be presented at EULAR 2022 in Copenhagen, Denmark, June 1-4.
3. Navarro-Compán V, Rudwaleit M, de Peyrecave N et al. Maintenance of response to bimekizumab over 3 years of treatment in patients with active ankylosing spondylitis: post-hoc analyses from the BE AGILE study and its open-label extension. To be presented at EULAR 2022 in Copenhagen, Denmark, June 1-4.
4. ClinicalTrials.gov. A Study to Evaluate the Efficacy and Safety of Bimekizumab in Subjects With Active Nonradiographic Axial Spondyloarthritis (BE MOBILE 1). Available at: https://clinicaltrials.gov/ct2/show/NCT03928704. Last accessed: May 2022.
5. ClinicalTrials.gov. A Study to Evaluate the Efficacy and Safety of Bimekizumab in Subjects With Active Ankylosing Spondylitis (BE MOBILE 2). Available at: https://www.clinicaltrials.gov/ct2/show/NCT03928743. Last accessed: May 2022
6. van der Heijde D, Gensler L, Deodhar A, et al. Dual Neutralisation of interleukin-17A and interleukin-17F With Bimekizumab in Patients With Active Ankylosing Spondylitis: Results From a 48-week Phase IIb, Randomised, Double-Blind, Placebo-Controlled, Dose-Ranging Study. Ann Rheum Dis. 2020;79(5):595-604.
7. ClinicalTrials.gov. A Study to Evaluate the Long Term Safety and Efficacy of Bimekizumab in Subjects With Ankylosing Spondylitis (BE AGILE 2). Available at: https://www.clinicaltrials.gov/ct2/show/NCT03355573. Last accessed: May 2022.

GL-N-BK-axSpA-2200010
Date of preparation: May 2022

8. Deodhar A. Understanding Axial Spondyloarthritis: A Primer for Managed Care. Am J Manag Care. 2019;25:S319-S330.
9. 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.
10. 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.
11. 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.
12. ClinicalTrials.gov. A Study to Test the Efficacy and Safety of Bimekizumab in the Treatment of Subjects with Active Psoriatic Arthritis (BE OPTIMAL). Available at: https://www.clinicaltrials.gov/ct2/show/NCT03895203?term=BE+OPTIMAL&draw=2&rank=1 Last accessed: May 2022.
13. ClinicalTrials.gov. A Study to Evaluate the Efficacy and Safety of Bimekizumab in the Treatment of Subjects with Active Psoriatic Arthritis (BE COMPLETE). Available at: https://www.clinicaltrials.gov/ct2/show/NCT03896581 Last accessed: May 2022.
14. BIMZELX® (bimekizumab) EU Summary of Product Characteristics. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Last accessed: May 2022.

GL-N-BK-axSpA-2200010
Date of preparation: May 2022