UCB News

Positive Top-Line Results for BIMZELX®▼(bimekizumab) in Phase 3 Non-Radiographic Axial Spondyloarthritis Study

- The BE MOBILE 1 study met the primary and all ranked secondary endpoints, showing that bimekizumab improved outcomes in patients with active non-radiographic axial spondyloarthritis
- BE MOBILE 1 is the second Phase 3 study of bimekizumab across the spectrum of axial spondyloarthritis to report positive results, and together with the first study in ankylosing spondylitis, supports the potential of bimekizumab across the full disease spectrum
- UCB plans to submit regulatory applications for bimekizumab in axial spondyloarthritis in Q3 2022

Brussels, Belgium – 18th January 2022 – 07:00 CET – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, today announced positive top-line interim analysis results showing that the Phase 3 BE MOBILE 1 study met the primary and all ranked secondary endpoints.[1] BE MOBILE 1 is the first study to evaluate the efficacy and safety of BIMZELX® (bimekizumab) in adults with active non-radiographic axial spondyloarthritis (nr-axSpA).

In the BE MOBILE 1 study, bimekizumab demonstrated a statistically significant and clinically meaningful improvement over placebo in the proportion of patients who achieved the Assessment of SpondyloArthritis International Society 40 percent (ASAS40) response at week 16, the primary endpoint of the study.[1] ASAS40 measures improvements in disease across four different domains - patient global assessment of disease activity, spinal pain, physical function and inflammation.[2] The primary endpoint used in this study, ASAS40, set a high threshold for improvement in patient-reported outcomes, i.e., at least a 40 percent improvement relative to baseline.*

The study also met all ranked secondary endpoints. Patients treated with bimekizumab achieved significant improvements over placebo at week 16 in the signs and symptoms of disease as measured by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI); achievement of ASAS partial remission (PR) and Ankylosing Spondylitis Disease Activity Score (ASDAS) Major Improvement (MI); and the nocturnal spinal pain score.[1]

“We’re excited to share top-line findings from the second Phase 3 study in our clinical program of bimekizumab in axSpA. These positive results, together with the previously reported top-line data from the BE MOBILE 2 study, support the clinical potential of bimekizumab to improve patient outcomes across the full spectrum of axSpA, including both nr-axSpA and ankylosing spondylitis,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

“Today’s positive findings from the Phase 3 BE MOBILE 1 study provide clear evidence supporting bimekizumab in the treatment of nr-axSpA, and suggest that targeting IL-17F in addition to IL-17A may be a promising treatment approach for this painful, chronic rheumatic condition that often starts in young adulthood,” said Prof. Atul Deodhar, MD, MRCP, Professor of Medicine, Division of Arthritis and Rheumatic Diseases, Oregon Health & Science University, Portland, OR, U.S.

In BE MOBILE 1, the safety profile of bimekizumab was consistent with safety data seen in previous studies with no new observed safety signals.[1] The safety and efficacy of bimekizumab in nr-axSpA have not been established. Bimekizumab is not approved for use in nr-axSpA or ankylosing spondylitis, also known as radiographic axSpA, by any regulatory authority worldwide.

Results from the BE MOBILE 1 study will be presented at upcoming medical conferences and published in a peer-reviewed medical journal.

The top-line results from the BE MOBILE 1 study build on the positive top-line results from the BE MOBILE 2 study[3] in radiographic axSpA, reported in December 2021. Based on these results, UCB plans to submit regulatory applications for bimekizumab in axSpA in the United States and the European Union in Q3 2022.

* *ASAS40 is achieved when there is at least a 40 percent improvement relative to baseline, and an absolute improvement of at least two units on a 0-10 numeric rating scale in at least three of the four domains that make up the ASAS response criteria – patient global assessment of disease activity, spinal pain, physical function and inflammation - with no worsening in the remaining domain.*[2]

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 non-radiographic axial spondyloarthritis (nr-axSpA).[2] BE MOBILE is the first Phase 3 bimekizumab research programme to include patients from China in its study population. The 52-week study is ongoing with top-line interim analysis results presented above. For additional details on the study, visit BE MOBILE 1 on clinicaltrials.gov.

BE MOBILE 1 enrolled participants with active disease.[2] Study participants had to have adult-onset axial spondyloarthritis meeting Assessment of SpondyloArthritis International Society (ASAS) classification criteria, inflammatory back pain for at least three months and no definitive radiographic sacroiliitis confirmed by central reading.[2] Patients needed to demonstrate objective signs of inflammation by elevated C-reactive protein (CRP) and/or positive magnetic resonance imaging (MRI). Study participants also had to have either failed to respond to two different nonsteroidal anti-inflammatory drugs (NSAIDs) given at the maximum tolerated dose for a total of four weeks or have had a history of intolerance to or a contraindication to NSAID therapy.[2] Patients who had taken a tumor necrosis factor alpha (TNFα) inhibitor had to have experienced an inadequate response or intolerance to treatment.[2]

About Axial Spondyloarthritis
Non-radiographic axSpA (nr-axSpA) falls under the umbrella of axial spondyloarthritis (axSpA), which also includes ankylosing spondylitis, also known as radiographic axSpA.[4] AxSpA is a painful chronic inflammatory disease that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).[5] nr-axSpA is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.[4] The leading symptom of axSpA is inflammatory back pain that improves with exercise, but not with rest.[4] Fatigue and stiffness are additional key symptoms. Other common clinical features frequently include acute anterior uveitis (eye inflammation), enthesitis (inflammation of the points of insertion of tendons and ligaments into bone), peripheral arthritis, psoriasis, inflammatory bowel disease (chronic inflammation of the digestive tract) and dactylitis (inflammation of the fingers or toes).[4] The overall prevalence of axSpA is 0.2 percent to 1.4 percent of adults.[6,7] Approximately half of all patients with axSpA are patients with nr-axSpA.[4] Approximately two-thirds of patients with AS are men,[8] while nr-axSpA is more common among women with the disease.[8] AxSpA onset usually occurs before the age of 45, often in the 20s.[4] 10 to 40 percent of patients with nr-axSpA progress to ankylosing spondylitis over 2 to 10 years.[4]

About BIMZELX® (bimekizumab)
Bimekizumab is a humanized monoclonal IgG1 antibody that is designed to selectively and directly inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), two key cytokines driving inflammatory processes.[9]

In the European Union (EU)/European Economic Area (EEA) and in Great Britain, BIMZELX® is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[10,11] Bimekizumab is not approved in psoriasis by any other regulatory authority outside the EU/EEA and Great Britain. Regulatory reviews are underway in Australia, Canada, Japan, Switzerland and the United States.

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.

Please consult the summary of product characteristics in relation to other side effects, full safety and prescribing information.

European SmPC date of revision August 2021. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

Last accessed: January 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.*

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 more than 7 600 people in approximately 40 countries, the company generated revenue of €5.3 billion in 2020. 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: 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' 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.

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References

[1] Data on file. UCB. January 2022.
[2] 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: January 2022.
[3] Data on file. UCB. December 2021.
[4] Deodhar A. Understanding Axial Spondyloarthritis: A Primer for Managed Care. *Am J Manag Care.* 2019;25:S319-S330.
[5] 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.
[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] Boonen A, Sieper J, van der Heijde D, et al. The burden of non-radiographic axial spondyloarthritis. *Semin Arthritis Rheum*. 2015;44(5):556-562.
[9] 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.
[10] BIMZELX® (bimekizumab) EU Summary of Product Characteristics, August 2021. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Last accessed: January 2022.
[11] 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: January 2022.