

## Positive Top-Line Results for BIMZELX®▼ (bimekizumab) in Phase 3 Ankylosing Spondylitis Trial

- BE MOBILE 2 is a Phase 3 study evaluating the efficacy and safety of bimekizumab in the treatment of patients with active ankylosing spondylitis, also known as radiographic axial spondyloarthritis
- The trial met the primary endpoint and all ranked secondary endpoints with statistical significance

**Brussels, Belgium – 16<sup>th</sup> December, 2021 – 0700 CET - Regulated Information - Inside Information –** UCB, a global biopharmaceutical company, today announced positive top-line interim analysis results from the Phase 3 BE MOBILE 2 study, which is evaluating the efficacy and safety of BIMZELX® (bimekizumab) in adults with active ankylosing spondylitis, also known as radiographic axial spondyloarthritis (r-axSpA).<sup>1</sup> BE MOBILE 2 is one of two Phase 3 studies evaluating bimekizumab across the full spectrum of axSpA disease, which includes both radiographic and non-radiographic (nr)-axSpA.<sup>1,2,3</sup>

The BE MOBILE 2 study met its primary endpoint, as measured by the proportion of patients who achieved the Assessment of SpondyloArthritis International Society 40 (ASAS40) response at week 16, when compared to placebo.<sup>1</sup> ASAS40 measures improvements in disease across different domains, including patient global assessment of disease activity, spinal pain, physical function and inflammation.<sup>2</sup> 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, including significant improvements with bimekizumab over placebo at week 16 in patient-reported disease activity, 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.<sup>1</sup>

“Ankylosing spondylitis is a painful, chronic, inflammatory rheumatic disease that often starts in young adulthood. The encouraging top-line Phase 3 results reported today are consistent with the Phase 2 findings and suggest that bimekizumab has the potential to deliver clinically meaningful improvements in the key signs and symptoms of the disease,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. “Today’s findings for bimekizumab in ankylosing spondylitis follow closely behind the positive results in psoriatic arthritis reported last month and reinforce our continued commitment to advancing standards of care.”

In BE MOBILE 2, the safety profile of bimekizumab was consistent with safety findings seen in previous studies with no new observed safety signals.<sup>1</sup> The safety and efficacy of bimekizumab in ankylosing spondylitis have not been established, and it is not approved for use in ankylosing spondylitis by any regulatory authority worldwide.<sup>1</sup>

Results from the BE MOBILE 2 study will be presented at upcoming medical conferences and published in a peer-reviewed medical journal. BE MOBILE 2 is one of two parallel Phase 3 studies evaluating bimekizumab in the treatment of patients across the axSpA disease spectrum.<sup>1,2</sup> The second study, BE MOBILE 1, is evaluating the efficacy and safety of bimekizumab in the treatment of patients with active nr-axSpA<sup>3</sup> and is expected to report top-line results soon.

*\*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.<sup>2</sup>*

### 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 ankylosing spondylitis.<sup>2</sup> BE MOBILE is the first Phase 3 bimekizumab research programme to include patients from China in its study population. BE MOBILE 2 enrolled 332 participants with moderate to severe active

disease.<sup>2</sup> Study participants had to have no response 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.<sup>2</sup> Patients who had taken a tumor necrosis factor alpha (TNF $\alpha$ ) inhibitor had to have experienced an inadequate response or intolerance to treatment.<sup>2</sup> The 52-week study is ongoing with top-line interim analysis results presented above. For additional details on the study, visit [BE MOBILE 2 on clinicaltrials.gov](#).

### About Axial Spondyloarthritis

Ankylosing spondylitis, or radiographic axial spondyloarthritis, falls under the umbrella of axial spondyloarthritis (axSpA), which also includes non-radiographic (nr)-axSpA.<sup>4</sup> axSpA is a painful chronic inflammatory disease that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).<sup>5</sup> The leading symptom of axSpA is inflammatory back pain that improves with exercise, but not with rest.<sup>4</sup> 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).<sup>4</sup> The overall prevalence of axSpA is 0.2 percent to 1.4 percent of adults, similar to rheumatoid arthritis.<sup>6,7,8</sup> Approximately two-thirds of patients with ankylosing spondylitis are men,<sup>9</sup> while nr-axSpA is more common among women with the disease.<sup>9</sup> axSpA onset usually occurs before the age of 45, often in the 20s.<sup>4</sup> 10 to 40 percent of patients with nr-axSpA progress to ankylosing spondylitis over 2 to 10 years.<sup>4</sup>

### About BIMZELX<sup>®</sup> (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.<sup>10</sup>

In the European Union (EU)/European Economic Area (EEA) and in Great Britain, Bimzelx<sup>®</sup> is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.<sup>11,12</sup> 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<sup>®</sup> ▼ (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 ( $\geq 1/100$  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, 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](https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf)

Last accessed: December 2021.

▼ *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](http://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.

### Forward looking statements UCB

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

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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.

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