UCB News

Annals of the Rheumatic Diseases Publishes Results from Two Bimekizumab Phase 3 Studies in Axial Spondyloarthritis

- Publication of 24-week results from the BE MOBILE 1 and BE MOBILE 2 studies, evaluating bimekizumab, an IL-17A and IL-17F inhibitor, across the full spectrum of axial spondyloarthritis

Brussels (Belgium), 18 January 2023 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced that *Annals of the Rheumatic Diseases* has published 24-week results from the Phase 3 BE MOBILE 1 and BE MOBILE 2 studies, evaluating the efficacy and safety of bimekizumab in the treatment of adults with active axial spondyloarthritis (axSpA), including active non-radiographic axial spondyloarthritis (nr-axSpA; BE MOBILE 1) and active ankylosing spondylitis (AS; BE MOBILE 2), also known as radiographic axSpA.[1]

"BE MOBILE 1 and BE MOBILE 2 represent the first phase 3 studies to evaluate the inhibition of IL-17F in addition to IL-17A with bimekizumab across the spectrum of axSpA. In both studies, treatment with bimekizumab resulted in rapid and clinically relevant improvements in outcomes, compared with placebo. The observed depth of response as well as the consistency of results in nr-axSpA and AS reinforce our confidence in bimekizumab as a potential new treatment option across the full spectrum of the disease," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

The two phase 3 studies, BE MOBILE 1 and BE MOBILE 2, met all primary and ranked secondary endpoints at Week 16.[1] In both studies, a significantly higher proportion of patients treated with bimekizumab achieved statistically significant and clinically meaningful improvements in nr-axSpA and AS, as defined by the primary endpoint of Assessment of SpondyloArthritis international Society ≥40 percent improvement (ASAS40) response at Week 16 compared with placebo ($p<0.001$).[1] In patients who received bimekizumab from baseline, the proportion of patients achieving ASAS40 response continued to increase to Week 24, and in patients who switched from placebo to bimekizumab at Week 16, the ASAS40 responses at Week 24 reached similar levels to those seen in bimekizumab-randomized patients.[1] The safety profile of bimekizumab was consistent with safety data seen in previous studies, with no new observed safety signals.[1]

The publication of results from two Phase 3 axSpA studies in *Annals of the Rheumatic Diseases* closely follows UCB news in December 2022 that *The Lancet* published two articles detailing results from two Phase 3 studies evaluating bimekizumab in adult patients with active psoriatic arthritis (PsA).

In September 2022, UCB announced that the European Medicines Agency had accepted for regulatory review the marketing authorization application for bimekizumab for the treatment of adult patients with active axSpA and active PsA. The efficacy and safety of bimekizumab in the treatment of axSpA and PsA have not been established and it is not approved for the treatment of active axSpA or active PsA by any regulatory authority worldwide.

Notes to editors:

About BE MOBILE 1
BE MOBILE 1 was 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. For additional details on the study, see article published in *Annals of the Rheumatic Diseases*.[1]

About BE MOBILE 2
BE MOBILE 2 was 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. For additional details on the study, see article published in *Annals of the Rheumatic Diseases*.[1]

About Axial Spondyloarthritis
Axial Spondyloarthritis (axSpA), which includes both non-radiographic axSpA (nr-axSpA) and ankylosing spondylitis (AS), also known as radiographic axSpA (r-axSpA), is a chronic, immune-mediated, inflammatory disease.[2] nr-axSpA is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.[2] axSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).[2] The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise, but not with rest.[2] Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease and dactylitis.[2] The overall prevalence of axSpA is 0.3 percent to 1.3 percent of adults.[3,4] Approximately half of all patients with axSpA are patients with nr-axSpA.[2] axSpA onset usually occurs before the age of 45.[2] Approximately 10 to 40 percent of patients with nr-axSpA progress to AS over 2 to 10 years.[2]

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.[5,6] 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.[6,7] The label information may differ in other countries. Please check local prescribing information.

About BIMZELX® ▼ (bimekizumab) in the EU/EEA
In the EU/EEA, BIMZELX® is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[6]

BIMZELX® ▼ (bimekizumab) EU/EEA Important Safety Information in Psoriasis[6]
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. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

EU summary of product characteristics date of revision December 2022.

Last accessed: January 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*

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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 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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