UCB News

UCB Receives Positive CHMP Opinions for Bimekizumab for the Treatment of Adults with Psoriatic Arthritis and Axial Spondyloarthritis in the European Union

- Positive CHMP opinions are supported by data from four Phase 3 studies that evaluated bimekizumab in active psoriatic arthritis (BE COMPLETE and BE OPTIMAL) and active axial spondyloarthritis (BE MOBILE 1 and BE MOBILE 2)
- If approved by the European Commission, these would mark the second and third indications for bimekizumab
- The European Commission decision is expected within two months

Brussels (Belgium), 27th April 2023 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued positive opinions recommending granting marketing authorization for bimekizumab in the European Union (EU) for the treatment of adults with active axial spondyloarthritis (axSpA) and for adults with active psoriatic arthritis (PsA). AxSpA is an indication that spans both non-radiographic axSpA (nr-axSpA) and ankylosing spondylitis (AS), also known as radiographic axSpA (r-axSpA). If approved by the European Commission (EC), these would represent the second and third indications for bimekizumab in the EU, following its initial approval for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy in August 2021.[1]

"The positive CHMP opinion for two new indications for bimekizumab in Europe is a significant step towards our goal of delivering differentiated treatment options to patients. If approved, bimekizumab would be the first treatment for psoriatic arthritis and axial spondyloarthritis that inhibits IL-17F in addition to IL-17A. Positive results from the four Phase 3 clinical studies in PsA and axSpA showed that treatment with bimekizumab consistently resulted in deep levels of response that were rapid and sustained," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

In active PsA, the CHMP recommended approval of bimekizumab alone or in combination with methotrexate, for the treatment of adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs. The CHMP opinion is based on data from the Phase 3 BE COMPLETE and BE OPTIMAL studies recently published in *The Lancet*.[2,3] The two studies met their primary and all ranked secondary endpoints with statistical significance at week 16.[2,3] Long-term data from BE OPTIMAL showed that bimekizumab demonstrated sustained responses to week 52.[4]

In active axSpA, the CHMP recommended approval of bimekizumab for the treatment of adults with active nr-axSpA with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs, and for the treatment of adults with active AS (r-axSpA) who have responded inadequately or are intolerant to conventional therapy. The positive CHMP opinion is based on data from the Phase 3 BE MOBILE 1 and BE MOBILE 2 studies, recently published in *Annals of the Rheumatic Diseases*.[5] The two studies met their

primary and all ranked secondary endpoints with statistical significance at week 16.[5] Long-term data from both studies showed that bimekizumab demonstrated sustained responses to week 52.[6]

In all four studies (BE OPTIMAL, BE COMPLETE, BE MOBILE 1 and BE MOBILE 2) the safety data were consistent with previous studies with no new observed safety signals.[2,3,5]

The CHMP positive opinions on bimekizumab in active PsA and active axSpA will be referred to the EC, which will deliver a final decision within approximately two months. The marketing authorization will be valid in all member states of the European Union as well as Iceland, Norway, Northern Ireland and Liechtenstein.

Bimekizumab is currently approved in the European Union for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[1]

Notes to editors

About Psoriatic Arthritis
Psoriatic arthritis (PsA) is a serious, highly heterogeneous, chronic, systemic inflammatory condition affecting both the joints and skin, with a prevalence of 0.02 percent to 0.25 percent of the population, and 6 percent to 41 percent of patients with psoriasis.[7] Symptoms include joint pain and stiffness, skin plaques, swollen toes and fingers (dactylitis) and inflammation of the sites where tendons or ligaments insert into the bone (enthesitis).[8]

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.[9] nr-axSpA is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.[9] axSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).[9] The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise, but not with rest.[9] Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease and dactylitis.[9] The overall prevalence of axSpA is 0.3 percent to 1.4 percent of adults.[10,11] Approximately half of all patients with axSpA are patients with nr-axSpA.[9] axSpA onset usually occurs before the age of 45.[9] Approximately 10 to 40 percent of patients with nr-axSpA progress to AS over 2 to 10 years.[9]

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.[1,12,13] 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.[1,12] The label information may differ in other countries where approved. 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.[1]

UCB News

BIMZELX® ▼ (bimekizumab) EU/EEA Important Safety Information in Psoriasis[1]

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: April 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

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: 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.

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. BIMZELX® (bimekizumab) EU Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Last accessed: April 2023.
2. 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.
3. McInnes IB, Asahina A, Coates LC, et al. Bimekizumab in patients with psoriatic arthritis, naïve to biologic treatment: a randomised, double-blind, placebo-controlled, phase 3 trial (BE OPTIMAL). Lancet. 2023; 401(10370):25–37.
4. Ritchlin C, Coates L, McInnes I, et al. Bimekizumab treatment in biologic DMARD-naïve patients with active psoriatic arthritis: 52-week efficacy and safety results from a Phase 3, randomized, placebo-controlled, active reference study. Arthritis Rheumatol. 2022; 74 (suppl 9).
5. 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: April 2023.
6. Baraliakos X, Deodhar A, van der Heijde D, et al. Bimekizumab maintains improvements in efficacy endpoints and has a consistent safety profile through 52 weeks in patients with non-radiographic axial spondyloarthritis and ankylosing spondylitis: results from two parallel Phase 3 studies. Arthritis Rheumatol. 2022; 74 (suppl 9).
7. Ogdie A, Weiss P. The epidemiology of psoriatic arthritis. Rheum Dis Clin North Am. 2015;41(4):545–568.
8. Mease PJ, Armstrong AW. Managing patients with psoriatic disease: the diagnosis and pharmacologic treatment of psoriatic arthritis in patients with psoriasis. Drugs. 2014;74(4):423–441.
9. Deodhar A. Understanding axial spondyloarthritis: A primer for managed care. Am J Manag Care. 2019;25:S319–S330.
10. 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.
11. 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.
12. BIMZELX® (bimekizumab) GB Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/12834/smpc - gref. Last accessed: April 2023.
13. 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.