UCB News

Positive Top-Line Results for BIMZELX®▼(bimekizumab) in Second Phase 3 Psoriatic Arthritis Study

- The BE COMPLETE study evaluated bimekizumab in adults with active psoriatic arthritis who were inadequate responders or intolerant to anti-TNF treatment
- BE COMPLETE is the second positive Phase 3 study for bimekizumab in active psoriatic arthritis, meeting its primary and all ranked secondary endpoints with statistically significant and clinically meaningful results
- UCB plans to submit regulatory applications for bimekizumab in psoriatic arthritis in Q3 2022

Brussels, Belgium – 21st January 2022 – 07:00 CET – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, today announced positive top-line results from the Phase 3 BE COMPLETE study, which evaluated the efficacy and safety of BIMZELX® (bimekizumab) in the treatment of adults with active psoriatic arthritis, who were inadequate responders or intolerant to anti-tumor necrosis factor-alpha (anti-TNF-α) therapy.[1]

BE COMPLETE met its primary endpoint, demonstrating that significantly more patients treated with bimekizumab achieved 50 percent or greater improvement in signs and symptoms of disease from baseline, compared with placebo, as measured by the American College of Rheumatology (ACR) 50 response at week 16.[1]

The study also met all ranked secondary endpoints. Bimekizumab showed significant improvements over placebo at week 16 in physical function, as measured by Health Assessment Questionnaire-Disability Index (HAQ-DI); skin clearance, as measured by at least a 90 percent improvement in the Psoriasis Area and Severity Index (PASI90); physical health status, as measured by the Short Form 36-item Health Survey (SF-36) Physical Component Summary (PCS) score; and low disease activity, as measured by the Minimal Disease Activity (MDA) index.[1]

“Psoriatic arthritis is a chronic inflammatory condition affecting both the joints and skin. The positive top-line results from the Phase 3 BE COMPLETE study show the potential of bimekizumab to improve the signs and symptoms of active psoriatic arthritis in a patient population who were inadequate responders or intolerant to anti-TNF therapy,” said Dr Joseph F. Merola, MD, MMSc, Associate Professor, Harvard Medical School and Brigham and Women’s Hospital, Boston, MA, U.S.

“The BE COMPLETE results mark the latest positive data in a series of four Phase 3 readouts for bimekizumab in the treatment of psoriatic arthritis and axial spondyloarthritis. We believe that these consistent and robust results have the potential to elevate the standard of care for patients,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. “Both psoriatic arthritis studies in the program used ACR50 as the primary outcome measure. The positive findings in both studies highlight the clinical potential of bimekizumab in psoriatic arthritis for both biologic naïve and anti-TNF therapy experienced patients.”

In BE COMPLETE, 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 psoriatic arthritis have not been established, and it is not approved for use in psoriatic arthritis by any regulatory authority worldwide.[1]

Full results from the BE COMPLETE study will be presented at upcoming medical conferences and published in a peer-reviewed medical journal.

The top-line results from the BE COMPLETE study build on the positive top-line interim analysis results from the Phase 3 BE OPTIMAL study in adults with active psoriatic arthritis, who were biologic disease-modifying anti-rheumatic drug (bDMARD) naïve, reported in November 2021.[2] Based on these results, UCB plans to submit regulatory applications for bimekizumab in psoriatic arthritis in the United States and the European Union in Q3 2022.

About BE COMPLETE
BE COMPLETE is a randomized, multicenter, double-blind, placebo-controlled, parallel group, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in adults with active psoriatic arthritis who were inadequate responders or intolerant to anti-tumor necrosis factor-alpha (anti-TNF-α) therapy.[3] BE COMPLETE enrolled 400 participants with disease for at least six months prior to screening, and a baseline tender joint count (TJC) ≥ three out of 68 and swollen joint count (SJC) ≥ three out of 66.[3] All enrolled study participants had a history of inadequate response (lack of efficacy after at least three months of therapy at an approved dose) or intolerance to treatment with one or two tumor necrosis factor alpha (TNFα) inhibitors for either psoriatic arthritis or psoriasis.[3] For additional details on the study, visit BE COMPLETE on clinicaltrials.gov.

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 0.05 percent to 0.25 percent of the population, and 6 percent to 41 percent of patients with psoriasis.[4] Symptoms include joint pain and stiffness, skin plaques, swollen toes and fingers (dactylitis), and persistent inflammation of the sites where tendons or ligaments insert into the bone (enthesitis).[5]

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.[6]

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.[7,8] In the U.S., bimekizumab is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe plaque psoriasis in adults.

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.

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 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 Data on file. UCB. November 2021.
3 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: January 2022.
4 Ogdie A, Weiss P. The Epidemiology of Psoriatic Arthritis. *Rheum Dis Clin North Am.* 2015; 41(4): 545–568.
5 Mease PJ, Armstrong AW. Managing patients with psoriatic disease: the diagnosis and pharmacologic treatment of psoriatic arthritis in patients with psoriasis. *Drugs.* 2014; 74:423-441.
6 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.
7 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.
8 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.