UCB News

UCB Announces First Detailed Data from Two Phase 3 Bimekizumab Studies in Psoriatic Arthritis to be Presented at EULAR 2022

- First presentations from the BE OPTIMAL and BE COMPLETE studies evaluating bimekizumab in the treatment of adults with active psoriatic arthritis who were biologic-naïve and TNF-inadequate responders, respectively
- A higher proportion of patients treated with bimekizumab vs. placebo achieved improvements in joint symptoms at week 16 as measured by ACR50, with a consistent clinical response across biologic-naïve (43.9 percent vs. 10.0 percent; p<0.001) and TNF-inadequate responder populations (43.4 percent vs. 6.8 percent; p<0.001)
- At week 16, a greater proportion of bimekizumab-treated patients achieved high levels of skin clearance, PASI90, vs. placebo, with a consistent clinical response across populations (61.3 percent vs. 2.9 percent for biologic naïve and 68.8 percent vs. 6.8 percent for TNF-inadequate responders; p<0.001 for each)
- At week 16, over 40 percent of bimekizumab-treated patients vs. placebo achieved minimal disease activity in both studies (p<0.001)

Brussels (Belgium), 23 May 2022 – 8:30 (CEST) – UCB, a global pharmaceutical company, today announced detailed results from two Phase 3 studies which evaluated the efficacy and safety of bimekizumab versus placebo in the treatment of adults with active psoriatic arthritis who were biologic disease-modifying anti-rheumatic drug naïve (BE OPTIMAL) and in adults who had an inadequate response or intolerance to tumour necrosis factor inhibitors (BE COMPLETE).[1,2] 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.

Both studies met their primary endpoint of ACR50 at week 16 and all ranked secondary endpoints compared with placebo with statistical significance.[1,2] At week 16, patients treated with bimekizumab achieved clinically relevant improvements over placebo in both joint and skin symptoms with efficacy outcomes consistent across both biologic-naïve and TNF-inadequate responder populations.[1,2] In addition, at week 16, over 40 percent of patients in both studies achieved a minimal disease activity response compared with placebo.[1,2] The safety profile of bimekizumab was consistent with safety

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data seen in previous studies with no new observed safety signals.[1,2] The results will be presented at the European Congress of Rheumatology, EULAR 2022, in Copenhagen, Denmark, June 1-4.[1,2]

"Our Phase 3 clinical studies with bimekizumab used ACR50 at week 16 as the primary endpoint reflecting our goal to raise the treatment bar for people with psoriatic arthritis. Results show that bimekizumab addressed the debilitating joint symptoms of active psoriatic arthritis, while also providing high levels of skin clearance compared to placebo," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. "Importantly, the consistent findings seen across populations suggest that bimekizumab can provide a similar clinical response in patients that have an inadequate response or intolerance to TNF inhibitors, and in patients that are new to biologics."

"Today's findings from the BE OPTIMAL and BE COMPLETE studies provide clear evidence supporting the potential of bimekizumab, a dual IL-17A and IL-17F inhibitor, in the treatment of active psoriatic arthritis. This painful, chronic condition can greatly impact patients' lives. Achieving minimal disease activity is an important goal of treatment, that can ultimately lead to improved quality of life for people with psoriatic arthritis," said Dr Joseph F. Merola, MD, MMSc, Associate Professor, Harvard Medical School and Brigham and Women's Hospital, Boston, MA, U.S.

Data from BE COMPLETE (16-week analysis) and BE OPTIMAL (24-week interim analysis)

Joint Symptoms: In both studies, patients treated with bimekizumab (160 mg every four weeks [Q4W]) achieved statistically significant improvements in the primary endpoint of at least 50 percent or greater improvement from baseline in the American College of Rheumatology response criteria (ACR50) at week 16, compared with placebo.[1,2]

- In BE OPTIMAL, at week 16, 43.9 percent (n=189/431) of biologic naïve patients treated with bimekizumab achieved ACR50 versus 10.0 percent (n=28/281) of patients on placebo; $p<0.001$.[1]
- In BE COMPLETE, at week 16, 43.4 percent (n=116/267) of TNF-inadequate responder patients treated with bimekizumab achieved ACR50 versus 6.8 percent (n=9/133) of patients on placebo; $p<0.001$.[2]

Skin Symptoms: In both studies, patients treated with bimekizumab achieved statistically significant improvements in levels of skin clearance, as measured by the ranked secondary endpoint of at least a 90 percent improvement in the Psoriasis Area and Severity Index (PASI90) at week 16, compared with placebo.[1.2]

- In BE OPTIMAL, at week 16, 61.3 percent (n=133/217) of biologic naïve patients treated with bimekizumab achieved PASI90 versus 2.9 percent (n=4/140) on placebo; $p<0.001$.[1]
- In BE COMPLETE, at week 16, 68.8 percent (n=121/176) of TNF-inadequate responder patients treated with bimekizumab achieved PASI90 versus 6.8 percent (n=6/88) on placebo; $p<0.001$.[2]

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Minimal Disease Activity: In both studies, a significantly higher proportion of patients treated with bimekizumab achieved the ranked secondary endpoint of Minimal Disease Activity (MDA) response, compared with placebo at week 16.[1,2]

- In BE OPTIMAL, at week 16, 45.0 percent (n=194/431) of biologic-naïve patients treated with bimekizumab achieved MDA versus 13.2 (n=37/281) percent on placebo; p<0.001.[1]
- In BE COMPLETE, at week 16, 44.2 percent (n=118/267) of TNF-inadequate responder patients treated with bimekizumab achieved MDA versus 6.0 percent (n=8/133) on placebo; p<0.001.[2]

"In the BE OPTIMAL and BE COMPLETE studies, bimekizumab demonstrated clinically relevant improvements in musculoskeletal and skin outcomes for people with psoriatic arthritis compared with placebo. In addition, results from the BE OPTIMAL study show that treatment with bimekizumab was associated with inhibition of structural joint damage progression by week 16," said Professor Iain McInnes, Vice Principal and Head of College, University of Glasgow, Scotland.

Additional Outcomes

- In BE OPTIMAL, treatment with bimekizumab compared with placebo was associated with a statistically significant inhibition of progression of structural joint damage at week 16, as measured by mean change from baseline in the van der Heijde modified Total Sharp Score (vdHmTSS), a ranked secondary endpoint.[1]

- The clinical response in both studies was rapid, with separation from placebo observed from week two in BE OPTIMAL (ACR20; p<0.001, nominal, not controlled for multiplicity) and week four in BE COMPLETE (ACR50; p<0.001, nominal, not controlled for multiplicity).[1,2]

- In BE OPTIMAL, response rates continued to improve to week 24: 45.5 percent (n=196/431) of patients treated with bimekizumab achieved ACR50 and 35.9 percent (n=101/281) of patients switching from placebo to bimekizumab at week 16, i.e following an eight week treatment duration; 72.8 percent (n=158/217) of bimekizumab-treated patients achieved PASI90 and 61.4 percent (n=86/140) of patients switching from placebo to bimekizumab at week 16; 48.5 percent (n=209/431) of patients treated with bimekizumab achieved MDA and 37.7 percent (n=106/281) switching from placebo to bimekizumab at week 16.[1]

- An active reference arm, of adalimumab, was included in the BE OPTIMAL study. The study was not powered for statistical comparisons with the bimekizumab treatment group or placebo. At week 16, 45.7 percent (n=64/140), 41.2 percent (n=28/68) and 45.0 percent (n=63/140) of patients treated with adalimumab achieved ACR50, PASI90 and MDA, respectively.[1]

In BE OPTIMAL, over 16 weeks, 59.9 percent of patients treated with bimekizumab had ≥ one treatment emergent adverse event (TEAE) versus 49.5 percent of patients on placebo and 59.3 percent on adalimumab.[1] The three most frequent TEAEs (≥5 percent in any treatment arm) were

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nasopharyngitis (9.3 percent for bimekizumab; 4.6 percent for placebo and 5.0 percent for adalimumab), upper respiratory tract infection (4.9 percent for bimekizumab; 6.4 percent for placebo and 2.1 percent for adalimumab) and increased alanine aminotransferase (0.7 percent for bimekizumab; 0.7 percent for placebo and 5.0 percent for adalimumab).[1] Candida infections were reported in 2.6 percent of bimekizumab-treated patients, 0.7 percent on placebo and 0 percent on adalimumab.[1] The incidence of serious adverse events (SAEs) was low: 1.6 percent of patients treated with bimekizumab versus 1.1 percent on placebo and 1.4 percent on adalimumab.[1] No cases of systemic candidiasis, inflammatory bowel disease (IBD), major adverse cardiovascular events (MACE) or uveitis were reported.[1]

In BE COMPLETE, over 16 weeks, 40.1 percent of patients treated with bimekizumab had ≥ one TEAE versus 33.3 percent of patients on placebo.[2] The three most frequent TEAEs for patients treated with bimekizumab were nasopharyngitis (3.7 percent; 0.8 percent for placebo), oral candidiasis (2.6 percent; 0 percent for placebo) and upper respiratory tract infection (2.2 percent; 1.5 percent for placebo).[2] Two patients on bimekizumab discontinued treatment due to a TEAE (0.7 percent). The incidence of SAEs was low: 1.9 percent of patients treated with bimekizumab versus 0 percent on placebo, and none led to discontinuation.[2] No cases of systemic candidiasis, IBD, MACE, venous thromboembolism (VTE) or uveitis were reported.[2]

Notes to editors :

About BE OPTIMAL

BE OPTIMAL is a randomized, multicenter, double-blind, placebo-controlled, active reference (adalimumab), parallel-group, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in the treatment of adult patients with active psoriatic arthritis, who are biologic disease-modifying anti-rheumatic drug naïve.[3] The study is ongoing with 24-week interim analysis presented above. For additional details on the study, visit BE OPTIMAL on clinicaltrials.gov.[3]

About BE COMPLETE

BE COMPLETE was 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 and an inadequate response to tumor necrosis factor-alpha inhibitors (TNFαi).[4] 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 TNFαi for either psoriatic arthritis or psoriasis.[4] For additional details on the study, visit BE COMPLETE on clinicaltrials.gov.[4]

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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.[5] 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).[6]

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.[7,10] Bimekizumab is in Phase 3 clinical development for the treatment of active psoriatic arthritis with 24-week interim analysis from the BE OPTIMAL study and 16-week analysis from the BE COMPLETE study to be presented at EULAR 2022.[1,2] In addition, bimekizumab is in development for the treatment of active axial spondyloarthritis with 24-week interim analysis results from BE MOBILE 1 (non-radiographic axial spondyloarthritis) and BE MOBILE 2 (ankylosing spondylitis) studies to be presented at EULAR 2022.[8,9]

About BIMZELX® ▼ (bimekizumab) in the European Union/European Economic Area

In the European Union (EU)/European Economic Area (EEA), BIMZELX® is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[10]

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

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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 March 2022

Last accessed: May 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*

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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.

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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'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.

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