Positive Top-Line Results from BIMZELX®▼(bimekizumab) Phase 3 Psoriatic Arthritis Study Demonstrated Significant Improvements in Joint and Skin Symptoms

- The BE OPTIMAL study met the primary endpoint and all ranked secondary endpoints with statistical significance.
- The study used the high treatment goal of ACR50 as the primary outcome measure.
- BE OPTIMAL is the first of two Phase 3 trials evaluating the efficacy and safety of bimekizumab in adults with active psoriatic arthritis.

UCB, a global biopharmaceutical company, today announced positive top-line interim analysis results from the Phase 3 BE OPTIMAL study assessing the efficacy and safety of BIMZELX® (bimekizumab), a dual IL-17A and IL-17F inhibitor, in the treatment of adults with active psoriatic arthritis, who are biologic disease-modifying anti-rheumatic drug naïve.1

BE OPTIMAL met the 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 This Phase 3 study used ACR50 as the primary outcome measure1 instead of ACR20, i.e. 50 percent versus 20 percent improvement from baseline.

The study also met all ranked secondary endpoints for this interim analysis. Among the ranked secondary endpoints, bimekizumab demonstrated significant improvements at week 16 over placebo in physical function, as measured by the 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); and joint radiographic progression, as measured by the van der Heijde modified Total Sharp Score (vdHmTSS).1

“Psoriatic arthritis causes painful debilitating joint and skin inflammation, which impacts mobility and quality of life for patients. At UCB, our aim is to support more patients in achieving control of their symptoms and we set high treatment goals in BE OPTIMAL. The clinically meaningful improvements seen in both joint and skin symptoms strengthen our belief that bimekizumab can address the unmet needs of patients with psoriatic arthritis,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

“Today’s encouraging findings from the BE OPTIMAL study show the potential of bimekizumab to improve a range of signs and symptoms in people with active psoriatic arthritis, and suggest that targeting IL-17F, in addition to IL-17A, may be a promising therapeutic approach for this disease,” said Professor Iain McInnes, Vice Principal and Head of College, University of Glasgow, Scotland.

The safety profile of bimekizumab was consistent with safety findings 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.

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

BE OPTIMAL is one of two Phase 3 studies evaluating bimekizumab in the treatment of active psoriatic arthritis. Results from the second study, evaluating bimekizumab in the treatment of patients who were inadequate responders or intolerant to anti-tumor necrosis factor-α (anti-TNF) therapy, are expected soon.2

About BE OPTIMAL
BE OPTIMAL is a randomized, multicenter, double-blind, placebo-controlled, non-inferential active reference arm (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 BE OPTIMAL enrolled 852 participants with disease for at least six months prior to

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screening, and a baseline tender joint count (TJC) ≥ three out of 68 and swollen joint count (SJC) ≥ three out of 66. The study is ongoing with top-line results from the week 24 interim analysis presented above. For additional details on the study, visit BE OPTIMAL 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 selectively and directly inhibits both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), two key cytokines driving inflammatory processes.6 Selective inhibition of IL-17F, in addition to IL-17A has been shown to suppress inflammation to a greater extent than IL-17A inhibition alone.6-7

About Bimzelx® in the EU/EEA*
In the EU, Bimzelx® is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.8

*EU/EEA means European Union/European Economic Area

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.
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.

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