UCB News

UCB announces a head-to-head study evaluating BIMZELX® ▼(bimekizumab) versus SKYRIZI® (risankizumab) in active psoriatic arthritis

- First Phase 3b study in psoriatic arthritis to evaluate the superiority of an IL-17A and IL-17F inhibitor to an IL-23 inhibitor
- This is the first head-to-head study in psoriatic arthritis to use ACR50 at Week 16 as a primary endpoint
- Study underscores UCB's belief in bimekizumab with top-line results expected in 2026

Brussels (Belgium), September 30, 2024 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced the start of BE BOLD, a head-to-head Phase 3b study, comparing BIMZELX® (bimekizumab), an IL-17A and IL-17F inhibitor, with SKYRIZI® (risankizumab), an IL-23 inhibitor, in the treatment of adults with active psoriatic arthritis (PsA). BE BOLD is the first head-to-head study in PsA evaluating the superiority of an IL-17A and IL-17F inhibitor to an IL-23 inhibitor.

"The conduct of head-to-head, evidence-based, clinical studies in psoriatic arthritis is important since they add to the existing scientific evidence available to healthcare professionals and patients and can help to make informed treatment decisions," said Philip J. Mease, MD, Director of Rheumatology Research at the Providence Swedish Medical Center and Clinical Professor at the University of Washington School of Medicine in Seattle, WA, U.S. "This is the first Phase 3b head-to-head study in psoriatic arthritis to utilize the primary endpoint of ACR50 at Week 16. This robust assessment is set to provide a meaningful comparison of bimekizumab vs. risankizumab on inflamed joints, one of the areas of most concern for many people living with psoriatic arthritis. We look forward to the results and the implications for future clinical practice."

"In moderate to severe plaque psoriasis UCB has conducted three head-to-head Phase 3/3b studies with bimekizumab versus commonly used biologics, and results from these studies showed that bimekizumab was superior to secukinumab, ustekinumab and adalimumab," said Fiona du Monceau, Executive Vice President, Head of Patient Evidence, UCB. "BE BOLD represents the fourth head-to-head study in the bimekizumab clinical trial program, the first to be conducted in psoriatic arthritis, and the first versus an IL-23 inhibitor. This study underscores our confidence in the potential of bimekizumab for people living with psoriatic disease. We look forward to communicating the top-line results in 2026."

BE BOLD is a multicentre, randomized, double-blind, risankizumab controlled, parallel-group study designed to evaluate the efficacy and safety of bimekizumab in adult study participants (n=~550) with active psoriatic arthritis. The study population will include adults with active psoriatic arthritis who are biologic treatment naïve or who had previous exposure to one tumour necrosis factor-inhibitor (TNFi) with an inadequate or intolerant response. The primary endpoint will assess American College of Rheumatology 50 (ACR50, i.e., 50 percent or greater improvement in the signs and symptoms of psoriatic arthritis) at Week 16. Key ranked secondary endpoints include minimal disease activity at Week 16, and the composite endpoint, ACR50 and PASI100 (complete skin clearance) at Week 16.

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Driven by science.

SKYRIZI® is a registered trademark of AbbVie Biotechnology Ltd.

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.[1] 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).[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.[3]

The therapeutic indications in the European Union are:
- Plaque psoriasis: Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[4]
- Psoriatic arthritis: Bimekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).[4]
- Axial spondyloarthritis: Bimekizumab is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP), and/or magnetic resonance imaging (MRI), who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs), and for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.[4]
- Hidradenitis suppurativa: Bimekizumab is indicated for the treatment of active moderate to severe hidradenitis suppurativa (HS; acne inversa) in adults with an inadequate response to conventional systemic HS therapy.[4]

BIMZELX® ▼ (bimekizumab) EU/EEA* Important Safety Information[4]

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%, 14.6%, 16.3%, 8.8% in plaque psoriasis, psoriatic arthritis, axial spondyloarthritis (axSpA) and hidradenitis suppurativa, respectively) and oral candidiasis (7.3%, 2.3%, 3.7%, 5.6% in PSO, PsA, axSpA and HS, respectively). Common adverse reactions (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, vulvovaginal mycotic infection (including vulvovaginal candidiasis), headache, rash, 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 to 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 initiated in patients with any clinically important active infection. Patients treated with bimekizumab should be

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instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops an infection the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy, treatment should be discontinued until the infection resolves. Prior to initiating treatment with bimekizumab, patients should be evaluated for tuberculosis (TB) infection. Bimekizumab should not be given in patients with active TB. 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 2024. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product- information_en.pdf

*EU/EEA means European Union/European Economic Area

▼ *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 9,000 people in approximately 40 countries, the company generated revenue of €5.3 billion in 2023. 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: 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.

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