UCB News

UCB Presents New Five-Year Data on BIMZELX® ▼(bimekizumab) in Ankylosing Spondylitis at ACR Convergence 2023

- Long-term data on bimekizumab in the treatment of adults with ankylosing spondylitis showed sustained improvements for up to five years with the safety profile consistent with previous observations

Brussels (Belgium), 10th November 2023 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced new long-term data from the BIMZELX® (bimekizumab) Phase 2b study BE AGILE and its open-label extension (OLE). Patients with ankylosing spondylitis (AS), also known as radiographic axial spondyloarthritis (r-axSpA), treated with bimekizumab, an IL-17A and IL-17F inhibitor, showed sustained improvements in signs and symptoms, disease activity, physical function and health-related quality of life for up to five years, with a consistent safety profile through five years of treatment.[1] These data are being presented this week at the American College of Rheumatology (ACR) Convergence 2023 in San Diego, U.S., November 10–15.

"There is a need for additional treatment options for people living with ankylosing spondylitis since many people do not achieve long-term disease control. The five-year bimekizumab data in ankylosing spondylitis demonstrated sustained improvements across multiple domains of disease and a safety profile consistent with previous observations," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

"This is the first report of ASAS40 five-year data in patients with ankylosing spondylitis to use a conservative non-responder imputation analysis. Using this method, the data showed that at least half of the patients treated with bimekizumab achieved sustained improvements through five years of treatment," said Professor Atul Deodhar, Professor of Medicine, Oregon Health & Science University, Division of Arthritis and Rheumatic Diseases, Portland, OR, U.S.

Bimekizumab is not approved in the U.S. for the treatment of AS. In the U.S., the efficacy and safety of bimekizumab for the treatment of AS have not been established. In the U.S., bimekizumab is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[2]

In the European Union (EU), bimekizumab is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[3] In the EU, bimekizumab, alone or in combination with methotrexate, is also 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.[3] Bimekizumab is also indicated in the EU for the treatment of adults with active non-radiographic axial spondyloarthritis 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 ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.[3]

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Highlights from the BE AGILE five-year data in AS
Of 255/303 (84.2 percent) patients who entered the OLE at Week 48, and received ≥1 bimekizumab dose, 202/255 (79.2 percent) completed to Week 256. Clinical improvements were sustained across the endpoints detailed below through Week 256 in patients receiving bimekizumab.[1]

- **ASAS40:** At the OLE entry visit (Week 48), 51.7 percent of patients who started the dose-blind period (n=296) achieved ASAS40, a 40 percent improvement response according to Assessment of Spondyloarthritis International Society (ASAS) criteria, and 49.7 percent of patients achieved ASAS40 at five years (Week 256; non-responder imputation).[1] Of patients who entered the OLE at Week 48 (n=249), 59.8 percent achieved ASAS40 at Week 48 and 59.0 percent at five years (Week 256; non-responder imputation).[1]

- **Disease Activity:** Mean reduction from baseline to Week 48 in Ankylosing Spondylitis Disease Activity Score (ASDAS, 3.9 to 2.1, respectively) in patients who entered the dose-blind period were sustained at five years (2.1, multiple imputation). At Week 48, 49.3 percent who started the dose-blind period (n=296) achieved low disease activity (LDA) status, as measured by ASDAS<2.1 and 41.6 percent of patients had ASDAS LDA at five years (Week 256; non-responder imputation).[1] Of patients who entered the OLE at Week 48 (n=249), 57.3 percent achieved ASDAS LDA at Week 48 with 66.0 percent at five years (Week 256; multiple imputation).[1]

  Mean reductions from baseline to Week 48 in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI, 6.5 to 3.0, respectively) in patients who entered the dose-blind period were sustained or further decreased to 2.5 at five years (Week 256; multiple imputation).[1] Responses for patients who entered the OLE were similar.[1]

- **Physical Function & Quality of Life:** Improvements in physical function, measured by the Bath Ankylosing Spondylitis Functional Index (BASFI) and mean improvements in quality of life measured by the Ankylosing Spondylitis Quality of Life questionnaire (ASQoL) were sustained to Week 256.[1]

Over five years, exposure adjusted incidence rates (EAIRs) per 100 patient years were 134.6 for any treatment emergent adverse event (TEAE) and 5.2 for serious TEAEs. The EAIR of *Candida* infections over 256 weeks at 2.6 was lower than in weeks 0–48 (7.5). All Candida infections were mild or moderate, and none were systemic.[1]

▼ *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.*

Notes to editors:

About BE AGILE
The dose-ranging BE AGILE study consisted of a 12-week double-blind, placebo-controlled period, then a dose-blind period to Week 48 where patients received bimekizumab 160 mg or 320 mg every four weeks (Q4W).[1] Patients completing Week 48 were eligible to enter the open-label extension (OLE) where all patients received bimekizumab 160 mg Q4W to Week 256.[1]

About Axial Spondyloarthritis (axSpA)
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.[4] nr-axSpA is defined clinically by the absence of definitive X-ray evidence of structural damage to the sacroiliac joints.[4] AxSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).[4] The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise, but not with rest.[4] Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease and dactylitis.[4] The overall prevalence of axSpA is 0.3 percent to 1.4 percent of adults.[5,6] Approximately half of all patients with axSpA are patients with nr-axSpA.[4] axSpA onset usually occurs before the age of 45.[4] Approximately 10 to 40 percent of patients with nr-axSpA progress to ankylosing spondylitis over 2 to 10 years.[4]

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]

Bimekizumab is not approved in the U.S. for the treatment of AS. In the U.S., the efficacy and safety of bimekizumab for the treatment of AS have not been established. In the U.S., bimekizumab is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[2]

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.[3]
- **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).[3]
- **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.[3]

The label information may differ in other countries where approved. Please check local prescribing information.

BIMZELX U.S. IMPORTANT SAFETY INFORMATION[2]

Suicidal Ideation and Behavior
BIMZELX® (bimekizumab-bkzx) may increase the risk of suicidal ideation and behavior (SI/B). A causal association between treatment with BIMZELX and increased risk of SI/B has not been established. Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or SI/B. Advise monitoring for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, advise to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.

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Date of preparation: November 2023

Infections
BIMZELX may increase the risk of infections. Do not initiate treatment with BIMZELX in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing BIMZELX. Instruct patients to seek medical advice if signs or symptoms suggestive of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, monitor the patient closely and do not administer BIMZELX until the infection resolves.

Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX. Avoid the use of BIMZELX in patients with active TB infection. Initiate treatment of latent TB prior to administering BIMZELX. Consider anti-TB therapy prior to initiation of BIMZELX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients for signs and symptoms of active TB during and after treatment.

Liver Biochemical Abnormalities
Elevated serum transaminases were reported in clinical trials with BIMZELX. Test liver enzymes, alkaline phosphatase and bilirubin at baseline, periodically during treatment with BIMZELX and according to routine patient management. If treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected, interrupt BIMZELX until a diagnosis of liver injury is excluded. Permanently discontinue use of BIMZELX in patients with causally associated combined elevations of transaminases and bilirubin. Avoid use of BIMZELX in patients with acute liver disease or cirrhosis.

Inflammatory Bowel Disease
Cases of inflammatory bowel disease (IBD) have been reported in patients treated with IL-17 inhibitors, including BIMZELX. Avoid use of BIMZELX in patients with active IBD. During BIMZELX treatment, monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.

Immunizations
Prior to initiating therapy with BIMZELX, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with BIMZELX.

Most Common Adverse Reactions
Most common adverse reactions (≥ 1%) are upper respiratory infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes Simplex Infections, acne, folliculitis, other Candida infections, and fatigue.

BIMZELX® ▼ (bimekizumab) EU/EEA* Important Safety Information[3]

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%, 14.6%, 16.3% in plaque psoriasis (PSO), psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA), respectively) and oral candidiasis (7.3%, 2.3%, 3.7% in PSO, PsA and axSpA, respectively). Common adverse reactions (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, 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.

GL-BK-2300035
Date of preparation: November 2023

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 initiated 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. 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: June 2023.

https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

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*EU/EEA means European Union/European Economic Area

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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 8,700 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: 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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