UCB News

BIMZELX® (bimekizumab) Receives Approval in Japan for the Treatment of Psoriatic Arthritis, Non-radiographic Axial Spondyloarthritis and Ankylosing Spondylitis

- Bimekizumab is the first IL-17A and IL-17F inhibitor to receive regulatory approval in Japan for the treatment of psoriatic arthritis (PsA), non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS) in adult patients
- The extended approval for bimekizumab in Japan follows its first approval in January 2022 for plaque psoriasis, generalized pustular psoriasis, and psoriatic erythroderma
- This represents the third approval by regulatory authorities around the world for bimekizumab in PsA, nr-axSpA and AS

Brussels (Belgium), 27th December 2023 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved BIMZELX® (bimekizumab) for the treatment of adults with psoriatic arthritis (PsA), non-radiographic axSpA (nr-axSpA) and ankylosing spondylitis (AS) who are not sufficiently responding to existing treatments.[1] The new indications for bimekizumab in Japan follow its first approval in January 2022 for the treatment of plaque psoriasis, generalized pustular psoriasis, and psoriatic erythroderma.[1] Bimekizumab is the first IL-17A and IL-17F inhibitor to receive regulatory approval in Japan for the treatment of PsA, nr-axSpA and AS in adult patients. This milestone also represents the third approval for bimekizumab in PsA, nr-axSpA and AS in 2023, following approval for these additional indications in countries of the European Union/European Economic Area and in Great Britain in June and August 2023, respectively.[2,3]

"We are excited to bring bimekizumab as a new treatment option for people in Japan living with psoriatic arthritis and those living with axial spondyloarthritis. The extended approval for bimekizumab in Japan beyond the psoriasis indications expands the reach of the first dual IL-17A and IL-17F inhibitor and marks another step forward in our ambition to transform lives," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

Bimekizumab was approved in Japan for the treatment of adult patients with PsA. The approval is based on data from the Phase 3 BE COMPLETE and BE OPTIMAL studies published as back-to-back manuscripts in *The Lancet*.[4,5] Bimekizumab was also approved in Japan for the treatment of adult patients with ankylosing spondylitis and non-radiographic axial spondyloarthritis. The approval is based on data from the Phase 3 BE MOBILE 1 and BE MOBILE 2 studies, published in *Annals of the Rheumatic Diseases*.[6] The safety profile of bimekizumab in all four studies was consistent with safety data seen in previous studies with no new observed safety signals.[4,5,6]

UCB is committed to bringing bimekizumab to patients with PsA and axSpA worldwide. Regulatory reviews are underway in other countries including Australia, Canada, Switzerland and China (axSpA only).

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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.[7] 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).[8]

About Axial Spondyloarthritis

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.[9] nr-axSpA is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.[9] axSpA is a painful condition that primarily affects the spine and the joints linking the pelvis and lower spine (sacroiliac joints).[9] The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise but not with rest.[9] Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease and dactylitis.[9] The overall prevalence of axSpA is 0.3 percent to 1.3 percent of adults.[10,11] Approximately half of all patients with axSpA are patients with nr-axSpA.[9] axSpA onset usually occurs before the age of 45.[9] Approximately 10 to 40 percent of patients with nr-axSpA progress to AS over 2 to 10 years.[9]

About BE OPTIMAL and BE COMPLETE

The safety and efficacy of bimekizumab (160 mg every four weeks) were evaluated in adult patients with active psoriatic arthritis (PsA) in two phase 3 multicentre, randomized, double-blind, placebo-controlled studies (BE OPTIMAL and BE COMPLETE).[4,5] The BE OPTIMAL study evaluated 852 patients not previously exposed to any biologic disease-modifying anti-rheumatic drug (bDMARD-naïve) for the treatment of active psoriatic arthritis.[4] The BE COMPLETE study evaluated 400 patients with an inadequate response or intolerance to treatment with one or two tumour necrosis factor-alpha inhibitors (TNFi-IR) for active psoriatic arthritis.[5] Detailed findings from the BE OPTIMAL and BE COMPLETE studies are published in The Lancet.[4,5]

About BE MOBILE 1 and BE MOBILE 2

The efficacy and safety of bimekizumab (160 mg every four weeks) were evaluated in 586 adult patients with active axial spondyloarthritis (axSpA) in two phase 3 multicenter, randomized, double-blind, placebo-controlled studies, one in non-radiographic axSpA (nr-axSpA; BE MOBILE 1) and one in ankylosing spondylitis (AS; BE MOBILE 2), also known as radiographic axSpA.[6] The BE MOBILE 1 and BE MOBILE 2 studies evaluated 254 and 332 patients, respectively.[6] Detailed findings from the BE MOBILE 1 and BE MOBILE 2 studies are published in the Annals of the Rheumatic Diseases.[6]

About bimekizumab▼ in the EU

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.[12] 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.[2]
- **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).[2]

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- **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.[2]

BIMZELX® ▼ (bimekizumab) EU/EEA* Important Safety Information[2]

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.

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: November 2023.
https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

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*EU/EEA: European Union/European Economic Area

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▼ *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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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.

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