UCB News

UCB Receives New European Commission Approvals for BIMZELX® ▼ (bimekizumab) for the Treatment of Psoriatic Arthritis and Axial Spondyloarthritis

- Bimekizumab is the first and only IL-17A and IL-17F inhibitor approved in the European Union for active psoriatic arthritis (PsA) and active axial spondyloarthritis (axSpA)
- Approval in PsA is supported by two Phase 3 studies where bimekizumab showed improvements vs. placebo in joint and skin symptoms across biologic naïve and TNF inhibitor-inadequate responder populations
- Approval in axSpA is supported by two Phase 3 studies where bimekizumab showed improvements vs. placebo in signs, symptoms and disease activity across the spectrum of disease

Brussels (Belgium), 7th June 2023 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced that the European Commission (EC) has granted marketing authorisation for BIMZELX® (bimekizumab) for the treatment of adults with active psoriatic arthritis (PsA) and adults with active axial spondyloarthritis (axSpA) including non-radiographic axSpA (nr-axSpA) and ankylosing spondylitis (AS), also known as radiographic axSpA. These approvals in the European Union (EU) represent the first marketing authorizations for bimekizumab in PsA and axSpA worldwide, and the second and third indications for bimekizumab in the EU, following its approval for the treatment of moderate to severe plaque psoriasis in August 2021.[1]

"The European Commission's parallel approval of bimekizumab in PsA and axSpA builds on the momentum created since its first approval in moderate to severe plaque psoriasis and marks an exciting milestone offering healthcare professionals and patients the first IL-17A and IL-17F inhibitor for treatment of these diseases," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. "The extended approval for bimekizumab in the European Union reflects our commitment to address unmet patient needs, improve patient outcomes and raise standards of care."

In PsA, bimekizumab is approved alone or in combination with methotrexate for the treatment of adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).[1] In axSpA, bimekizumab is approved for the treatment of adults with active nr-axSpA 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 AS who have responded inadequately or are intolerant to conventional therapy.[1]

Bimekizumab in PsA: Highlights from BE OPTIMAL and BE COMPLETE

The EC approval in PsA is based on results from the Phase 3 BE OPTIMAL and BE COMPLETE studies.[1,2,3] In the two studies, bimekizumab met the primary endpoint of ACR50 response at Week 16 vs. placebo, and all ranked secondary endpoints.[1,2,3] Consistent results were seen across both biologic-naïve and TNF-inhibitor

inadequate responder (TNFi-IR) populations.[1 2,3] Clinical responses achieved at Week 16 were sustained up to Week 52 in BE OPTIMAL as assessed by ACR50, PASI90, PASI100 and Minimal Disease Activity (MDA).[1]

- **Joint Symptoms, ACR50:** In bDMARD-naive and TNFi-IR patients, 44 percent (n=189/431) and 43 percent (n=116/267) receiving bimekizumab achieved the primary endpoint of ACR50 response at Week 16, respectively, vs. 10 percent (n=28/281) and 7 percent (n=9/133) receiving placebo (p<0.0001).[2,3]
- **MDA:** In bDMARD-naive and TNFi-IR populations, 45 percent (n=194/431) and 44 percent (n=118/267) of patients receiving bimekizumab achieved the ranked secondary endpoint MDA at Week 16, respectively, vs. 13 percent (n=37/281) and 6 percent (n=8/133) receiving placebo (p<0.0001).[2,3]
- **Skin Symptoms, PASI100:** In bDMARD-naive and TNFi-IR populations, 47 percent (n=103/176) and 59 percent (n=103/176) of patients with baseline psoriasis affecting ≥3 percent body surface area receiving bimekizumab achieved complete skin clearance (PASI100; exploratory endpoint) at Week 16, respectively, vs. 2 percent (n=3/140) and 5 percent (n=4/88) receiving placebo.[2,3]

"The approval of bimekizumab in psoriatic arthritis provides rheumatologists and dermatologists in the European Union with a new treatment option. Data from the Phase 3 clinical studies demonstrated the consistently high thresholds of disease control achieved with bimekizumab vs. placebo in patients with psoriatic arthritis who were biologic naïve or TNF inhibitor-inadequate responders," said Professor Iain McInnes, University of Glasgow, College of Medical, Veterinary and Life Sciences, Glasgow, Scotland.

In BE OPTIMAL, the most frequent treatment-emergent adverse events (TEAEs; 3 percent or more) for patients on bimekizumab up to Week 16 were nasopharyngitis, upper respiratory tract infection, headache, diarrhoea, oral candidiasis, pharyngitis and hypertension.[2] In BE COMPLETE, the most frequent TEAEs (2 percent or more) for patients on bimekizumab up to Week 16 were nasopharyngitis, oral candidiasis and upper respiratory tract infection.[3]

Bimekizumab in axSpA: Highlights from BE MOBILE 1 and BE MOBILE 2

The EC approval in axSpA is based on results from the Phase 3 BE MOBILE 1 and BE MOBILE 2 studies.[1,4] In the two studies, bimekizumab met the primary endpoint of Assessment of SpondyloArthritis international Society (ASAS) 40 response at Week 16 vs. placebo, and all ranked secondary endpoints.[4] ASAS40 responses were consistent across TNFi-naïve and TNFi-inadequate responder patients.[4] Clinical responses achieved at Week 16 were sustained in both nr-axSpA and AS patient populations up to Week 52 as assessed by ASAS40 and other endpoints.[1,5]

- **ASAS40:** In nr-axSpA and AS populations, 47.7 percent (n=61/128) and 44.8 percent (n=99/221) respectively of patients receiving bimekizumab achieved the primary endpoint of ASAS40 response at Week 16, vs. 21.4 percent (n=27/126) and 22.5 percent (n=25/111) receiving placebo (p<0.001).[4]
- **Low Disease Activity:** Low disease activity (ASDAS<2.1 combining ASDAS-Inactive Disease and ASDAS-Low Disease, an exploratory endpoint) was achieved at Week 16 by 46.2 percent of nr-axSpA patients and 44.9 percent of AS patients vs. 20.6 percent and 17.5 percent in the placebo group.[4] In the two studies, approximately 6 out of 10 patients treated with bimekizumab achieved ASDAS<2.1 at Week 52.[1]
- **Inflammation:** Sustained reduction of objective inflammatory signs in both sacroiliac joints and the spine was observed in nr-axSpA and AS patients treated with bimekizumab vs. placebo as assessed by magnetic resonance imaging at Week 16 and Week 52, an exploratory endpoint.[4,5]

In addition, in pooled data from BE MOBILE 1 and BE MOBILE 2, at Week 16, the proportion of patients developing a uveitis event was lower with bimekizumab (0.6 per cent) compared to placebo (4.6 percent). The

incidence of uveitis remained low with long-term treatment with bimekizumab (1.2/100 patient-years in the pooled Phase 2/3 studies).[1]

"Today's approval of a new treatment option for axial spondyloarthritis is welcome news to the European rheumatology community. In phase 3 clinical studies a greater proportion of patients treated with bimekizumab, compared with placebo, achieved high treatment targets with significant improvement in signs, symptoms and measures of disease activity across the full spectrum of disease, including non-radiographic and radiographic populations," said Professor Désirée van der Heijde, Professor of Rheumatology, Leiden University Medical Center, Leiden, the Netherlands.

The most frequently reported TEAEs (3 percent or more in any bimekizumab group in either trial) up to Week 16 were nasopharyngitis, upper respiratory tract infection, pharyngitis, diarrhoea, headache and oral candidiasis.[4]

Notes to editors:

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 multicentre, randomized, double-blind, placebo-controlled studies (BE OPTIMAL and BE COMPLETE).[1,2,3] The BE OPTIMAL study evaluated 852 patients not previously exposed to any biologic disease-modifying anti-rheumatic drug (bDMARD-naïve) for the treatment of psoriasis or psoriatic arthritis.[2] 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 either psoriatic arthritis or psoriasis.[3] Detailed findings from the BE OPTIMAL and BE COMPLETE studies are published in The Lancet.[2,3]

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 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.[1,4] The BE MOBILE 1 and BE MOBILE 2 studies evaluated 254 and 332 patients, respectively.[4] Detailed findings from the BE MOBILE 1 and BE MOBILE 2 studies are published in the Annals of the Rheumatic Diseases.[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.[1,6] 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.[1]
- **Psoriatic arthritis:** Bimekizumab is indicated alone or in combination with methotrexate, 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).[1]
- **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.[1]

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BIMZELX® ▼(bimekizumab) EU/EEA* Important Safety Information[1]

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: June 2023.

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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