New Long-Term Data on Bimekizumab in Psoriatic Arthritis and Axial Spondyloarthritis Presented at EULAR 2023

- In patients with psoriatic arthritis with prior inadequate response to tumour necrosis factor inhibitors, bimekizumab demonstrated sustained joint and skin clearance responses to week 52
- Across the spectrum of axial spondyloarthritis, bimekizumab demonstrated sustained reduction of inflammatory lesions of the sacroiliac joints and spine, as well as sustained improvements in the main peripheral manifestations of disease, to week 52

Brussels (Belgium), 31st May 2023 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced new long-term 52-week data from three Phase 3 studies – BE COMPLETE with its long-term extension study, BE MOBILE 1 and BE MOBILE 2 – evaluating the efficacy and safety profile of bimekizumab, an inhibitor of IL-17F in addition to IL-17A, in adults with active psoriatic arthritis (PsA), active non-radiographic axial spondyloarthritis (nr-axSpA) and active ankylosing spondylitis (AS), also known as radiographic axSpA (r-axSpA), respectively.1,2,3 These results from the bimekizumab phase 3 program in PsA and axSpA are being presented at the European Congress of Rheumatology, EULAR 2023, in Milan, Italy, May 31–June 3. The safety and efficacy of bimekizumab in PsA, nr-axSpA and r-axSpA have not been established, and it is not approved for use in PsA, nr-axSpA or AS by any regulatory authority worldwide.

“Psoriatic arthritis and axial spondyloarthritis are chronic and progressive inflammatory diseases requiring long-term management. The new long-term bimekizumab data presented at EULAR 2023 showed sustained clinical responses across multiple disease manifestations and patient populations up to one year. These results reinforce our belief in bimekizumab as a potential new future treatment for patients living with psoriatic arthritis and axial spondyloarthritis,” said Emmanuel Caeymaex, Executive Vice President, Immunology and U.S. Solutions, UCB.

Bimekizumab 52-week PsA data: patients with prior inadequate response to tumour necrosis factor inhibitors (TNFi-IR)
Key 52-week results from the BE COMPLETE open-label extension study (BE VITAL) are shared below and build on the previously announced 16-week results from the BE COMPLETE study and 52-week results from the BE OPTIMAL study.1

“The long-term data from BE COMPLETE showed that over six out of 10 patients continuously treated with bimekizumab achieved complete skin clearance and almost one in two had minimal disease activity at week 52. These results complement the previously reported 52-week results from the BE OPTIMAL study and highlight the consistent and sustained response seen with bimekizumab in both biologic-naïve and TNF inhibitor-experienced patients with psoriatic arthritis,” said Professor Iain McInnes, University of Glasgow, College of Medicinal Veterinary and Life Sciences, Glasgow, Scotland.
American College of Rheumatology (ACR) 50: At week 52, 51.7 percent of psoriatic arthritis patients (TNFi-IR) continuously treated with bimekizumab (160 mg every four weeks [Q4W]; n=267), and 40.6 percent of patients who switched from placebo to bimekizumab at week 16 (n=133) achieved ACR50.1±

Complete Skin Clearance (PASI100): At week 52, in patients with baseline psoriasis ≥3 percent body surface area, 65.9 percent of patients continuously treated with bimekizumab (n=176) and 60.2 percent of patients who switched from placebo to bimekizumab at week 16 (n=88) achieved complete skin clearance (PASI100).1±

Minimal Disease Activity (MDA): At week 52, 47.2 percent (n=126/267) of patients continuously treated with bimekizumab and 33.1 percent (n=44/133) of patients who switched from placebo to bimekizumab achieved MDA.1±

Over 52 weeks, 62.6 percent (n=243/388) of patients treated with bimekizumab had ≥1 treatment emergent adverse event (TEAE) and 5.9 percent (n=23/388) reported a serious TEAE.1 Candida infections were reported by 6.4 percent (n=25/388) of patients receiving bimekizumab with all cases reported as mild or moderate and none reported as systemic.1

Bimekizumab 52-week axSpA data: inflammation of the sacroiliac joints and spine and peripheral manifestations

Key 52-week results from the phase 3 BE MOBILE 1 and BE MOBILE 2 studies evaluating the effect of bimekizumab on inflammatory lesions of the sacroiliac joints (SIJ) and spine as measured objectively by magnetic resonance imaging (MRI), and on the main peripheral manifestations of axSpA are shared below and build on previously announced 16-week and 52-week results from BE MOBILE 1 and BE MOBILE 2.2,3

“Treatment with bimekizumab versus placebo reduced inflammation of the spine and sacroiliac joints as detected by magnetic resonance imaging. In the two studies, approximately one in two patients with MRI inflammation at baseline achieved MRI remission at week 16, which was sustained out to week 52,” said Xenofon Baraliakos, Professor of Internal Medicine and Rheumatology, Ruhr-University Bochum, Bochum, Germany.

Inflammation SIJ: At week 52, in the BE MOBILE 1 imaging sub-study, 80.0 percent (n=32/40) of patients with inflammation at baseline receiving continuous bimekizumab and 57.1 percent (n=20/35) who switched from placebo to bimekizumab at week 16 achieved remission in inflammatory lesions of the SIJs (Spondyloarthritis Research Consortium of Canada [SPARCC SIJ<2]); in BE MOBILE 2, 75.7 percent (n=28/37) receiving bimekizumab and 66.7 percent (n=12/18) who switched from placebo to bimekizumab at week 16 achieved remission in inflammatory lesions of the SIJ.2¥

Inflammation Spine: At week 52, in the BE MOBILE 1 imaging sub-study, 40.0 percent (n=6/15) of patients with inflammation at baseline receiving continuous bimekizumab and 27.3 percent (n=3/11) who switched from placebo to bimekizumab at week 16 achieved remission (Berlin Spine ≤2); in BE MOBILE 2, 76.7 percent (n=23/30) receiving continuous bimekizumab and 62.5 percent (n=10/16) who switched from placebo to bimekizumab at week 16 achieved remission.2¥

Enthesitis: At week 52, in BE MOBILE 1, 54.3 percent of patients receiving continuous bimekizumab (n=94) and 44.6 percent who switched from placebo to bimekizumab (n=92) at week 16 achieved resolution of enthesitis (Maastricht Ankylosing Spondylitis Enthesitis=0); in BE MOBILE 2, 50.8 percent...
receiving continuous bimekizumab (n=132) and 46.3 percent who switched from placebo to bimekizumab at week 16 (n=67) achieved resolution of enthesitis.3±

- **Peripheral arthritis:** At week 52, in BE MOBILE 1, 62.2 percent of patients receiving continuous bimekizumab (n=45) and 65.1 percent who switched from placebo to bimekizumab at week 16 (n=43) achieved resolution (Swollen Joint Count=0); in BE MOBILE 2, 72.7 percent receiving continuous bimekizumab (n=44) and 81.8 percent who switched from placebo to bimekizumab at week 16 (n=22) achieved resolution (Swollen Joint Count=0).3±

In addition, in the largest pool of bimekizumab phase 2b and phase 3 data available, the exposure-adjusted incidence rate of uveitis in patients with axSpA treated with bimekizumab (160 mg Q4W) remains low at 1.2/100 patient-years. In this pooled data, the total bimekizumab exposure was 2,034.4 patient-years (N=848) and 15.3 percent of patients (n=130) had a history of uveitis. All uveitis TEAEs reported were mild to moderate and one event led to discontinuation.4

**Notes to editors:**

±–Non-responder imputation
¥–Observed Case

**About BE COMPLETE**

BE COMPLETE was a 16-week randomized, double-blind, placebo-controlled study in which patients with active psoriatic arthritis and prior inadequate response to tumor necrosis factor inhibitors (TNFi-IR) were randomized (2:1) to bimekizumab (160 mg every four weeks [Q4W]; N=267) or placebo (N=133).1 Week 16 completers were eligible to enter the open-label extension up to one year.1 Patients initially randomized to placebo were switched to bimekizumab at week 16 and received 36 weeks’ bimekizumab treatment up to week 52.1 A total of 86.8 percent (n=347) of randomized patients completed week 52.1 The primary endpoint in the BE COMPLETE study was ACR50 at week 16 with ranked secondary endpoints including PASI90 at week 16 and minimal disease activity (MDA) at week 16, with other endpoints including complete skin clearance (PASI100) at week 16.5

**About BE MOBILE 1 and BE MOBILE 2** 2,3

The phase 3 studies BE MOBILE 1 and BE MOBILE 2 comprised a 16-week double-blind treatment period followed by a 36-week maintenance period. In BE MOBILE 1 and BE MOBILE 2, patients were randomized to bimekizumab (160 mg Q4W; N=128 for BE MOBILE 1 and N=221 for BE MOBILE 2) or to placebo (N=126 for BE MOBILE 1 and N=111 for BE MOBILE 2). Patients initially randomized to placebo were switched to bimekizumab (160 mg Q4W) at week 16. The primary endpoint in the BE MOBILE 1 and BE MOBILE 2 studies was ASAS40 at week 16.6

**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.7,8 In August 2021, bimekizumab was first approved in the European Union (EU)/European Economic Area (EEA) and in Great Britain, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.5,9 The label information may differ in other countries. Please check local prescribing information where approved.

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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 and 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.  

EU summary of product characteristics date of revision: May 2022.


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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References

1. Coates LC, Landewé R, McInnes IB, et al. Sustained efficacy and safety of bimekizumab in patients with active psoriatic arthritis and prior inadequate response to tumour necrosis factor inhibitors: Results from the phase 3 BE COMPLETE study and its open-label extension up to 1 year. Abstract #POS0231 presented at EULAR 2023, Milan, Italy.


