UCB News

# UCB presents new 4-year data for BIMZELX® ▼(bimekizumab) in moderate to severe plaque psoriasis at EADV 2024

- Responder analyses demonstrated that approximately nine out of ten patients treated with bimekizumab who achieved PASI90 at Year 1, and over seven out of ten patients who achieved complete skin clearance (PASI100) at Year 1, maintained this response to Year 4
- Switching adalimumab, secukinumab, or ustekinumab PASI90 non-responders to bimekizumab led to most patients (over 70 percent) rapidly achieving and maintaining PASI90 for up to four years, and a large proportion (over 40 percent) achieved complete skin clearance

**Brussels (Belgium), 25th September 2024 – 07:00 (CEST)** – UCB, a global biopharmaceutical company, today announced the presentation of new four-year data in patients with moderate to severe plaque psoriasis treated with bimekizumab, an IL-17A and IL-17F inhibitor. These post-hoc analyses include maintenance of response through four years in bimekizumab patients who achieved near-complete or complete skin clearance after one year, and the clinical response up to four years in patients switching to bimekizumab following an inadequate response to either adalimumab, ustekinumab, or secukinumab.[1,2] These data are presented at the 33rd European Academy of Dermatology and Venereology (EADV) Congress in Amsterdam, the Netherlands, 25–28 September 2024. In addition, the design and rationale behind the exploratory, multicentre, open-label Phase 3b bimekizumab study, BE UNIQUE, that is exploring the fast onset, high level and durability of clinical and molecular responses in patients with psoriatic disease are also shared.[3]

"Given the chronic nature of psoriasis, it is critically important to evaluate long-term response of treatments. Achieving completely clear skin is a key goal for people living with moderate to severe plaque psoriasis and results presented at EADV 2024 showed that over 7 out of 10 patients who achieved complete skin clearance after one year, maintained this response at four years," said Professor Richard Warren, Northern Care Alliance NHS Foundation Trust and The University of Manchester, United Kingdom.

GL-BK-2400101
Date of preparation: September 2024

"The four-year data presented at EADV 2024 demonstrate maintenance of complete skin clearance for patients continuing treatment with bimekizumab," said Fiona du Monceau, Executive Vice President, Head of Patient Evidence, UCB. "We are also proud to share the design of BE UNIQUE, a Phase 3b study investigating whether the durability of clinical response with bimekizumab is associated with molecular and cellular changes in skin, blood and joints of patients with psoriatic disease."

## Highlights from the bimekizumab abstracts presented at EADV 2024:

***Maintenance of response from end of pivotal trials through four years (post-hoc analysis):*** Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY pivotal Phase 3 trials, and their open-label extension (OLE), BE BRIGHT.[1] Included patients were randomized to bimekizumab 320 mg every four weeks (Q4W) to Week 16, then bimekizumab Q4W or every 8 weeks (Q8W) until OLE entry.[1] Data are reported here for the combined bimekizumab dose group.[1]

- Of the 771 patients forming this group, 89.6 percent (n=691) and 75.1 percent (n=579) were PASI90 and PASI100 responders at Year 1, respectively.[1†]
- Of the PASI90 responders at Year 1, 87.9 percent maintained PASI90 response at Year 4.[1‡]
- Of the PASI100 responders at Year 1, 74.2 percent maintained PASI100 response at Year 4.[1‡]

***Four-year analysis of patients switching after inadequate response to adalimumab, ustekinumab and secukinumab (post-hoc analysis):*** Included patients from the 56-week BE SURE (bimekizumab versus adalimumab) and 52-week BE VIVID (bimekizumab versus ustekinumab) who then entered the BE BRIGHT OLE, and also patients from the 48-week BE RADIANT (bimekizumab versus secukinumab) who then entered its OLE.[2] All patients received bimekizumab Q8W from OLE Week 16/48 (BE RADIANT/BE BRIGHT) or the next scheduled visit.[2]

- Of patients randomized to receive adalimumab at baseline who entered the OLE, 41.9 percent (n=54/129) did not have a PASI90 response at the time of switch to bimekizumab (Week 24).[2*]
    - Following switch from adalimumab and after 176 weeks of bimekizumab, 92.2 percent had a PASI90 response and 74.4 percent had a PASI100 response.[2‡]
- Of patients randomized to receive ustekinumab at baseline who entered the OLE, 33.3 percent (n=44/132) did not achieve PASI90 at the time of switch to bimekizumab (Week 52).[2*]
    - Following switch from ustekinumab and after 144 weeks of bimekizumab, 82.0 percent achieved PASI90 and 58.8 percent achieved PASI100.[2‡]
- Of patients randomized to receive secukinumab at baseline who entered the OLE, 18.5 percent (n=58/314) did not achieve PASI90 at the time of switch to bimekizumab (Week 48).[2*]

GL-BK-2400101
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- Following switch from secukinumab and after 96 weeks of bimekizumab, 71.7 percent achieved PASI90 and 39.8 percent achieved PASI100.[2‡]

***Design and rationale behind the Phase 3b BE UNIQUE study:*** BE UNIQUE is an ongoing multicentre Phase 3b study designed to investigate molecular and cellular changes associated with bimekizumab responses in patients with psoriasis and psoriatic arthritis.[3] The primary objective is to assess change in gene expression score on skin biopsies, using preselected genes based on bimekizumab's mechanism of action and psoriatic disease pathways.[3]

UCB previously shared four-year safety data on bimekizumab in the treatment of moderate to severe plaque psoriasis. Data showed that treatment-emergent adverse events were consistent or decreased with longer bimekizumab exposure, with no new safety signals.

**Notes to Editors:**

[†] Non-Responder Imputation
[‡] modified Non-Responder Imputation
* Observed Case

## About Plaque Psoriasis

Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin.[4] This skin condition affects men and women of all ages and ethnicities.[5] Psoriasis signs and symptoms can vary but may include red patches of skin covered with silvery-white scales; dry, cracked skin that may bleed; and thickened, pitted or ridged nails.[6] Psoriasis affects nearly three percent of the total population, or about 125 million people worldwide.[7]

## About BIMZELX® ▼ (bimekizumab) in the European Union/European Economic Area

The approved indications for bimekizumab▼ in the EU are:[8]

- Plaque psoriasis: Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
- 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).
- Axial spondyloarthritis: Bimekizumab is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by

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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.

- 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.

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

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

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5 percent, 14.6 percent, 16.3 percent, 8.8 percent in plaque psoriasis, psoriatic arthritis, axial spondyloarthritis (axSpA) and hidradenitis suppurativa, respectively) and oral candidiasis (7.3 percent, 2.3 percent, 3.7 percent, 5.6 percent 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 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

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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.

Last accessed: September 2024.

▼ *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**

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**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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## References

1. Gordon KB, Cather J, Pariser D, et al. Bimekizumab maintenance of response from the end of pivotal trials through 4 years: Results in patients with moderate to severe plaque psoriasis from BE BRIGHT. Abstract at EADV 2024, Amsterdam, the Netherlands.
2. Kokolakis G, Han G, Pariser G, et al. Bimekizumab long-term efficacy in patients with moderate to severe plaque psoriasis after switching from adalimumab, ustekinumab, or secukinumab: Results from up to 4 years of total treatment from BE BRIGHT and BE RADIANT. Abstract at EADV 2024, Amsterdam, the Netherlands.
3. Gudjonsson J, Merola J, Warren R, et al. Bimekizumab: Exploring the fast onset, high level, and durability of clinical and molecular responses in patients with psoriatic disease – Design and rationale behind the exploratory, multicentre, open-label phase 3b BE UNIQUE study. Abstract at EADV 2024, Amsterdam, the Netherlands.
4. Griffiths C, Armstrong A, Gudjonsson J, et al. Psoriasis. Lancet. 2021;397(10281):1301–15.
5. Parisi R, Iskandar I, Kontopantelis E, et al. National, regional, and worldwide epidemiology of psoriasis: systematic analysis and modelling study. BMJ. 2020;369:m1590.doi:10.1136/bmj.m1590.
6. National Institute of Arthritis and Musculoskeletal and Skin Diseases. https://www.niams.nih.gov/health-topics/psoriasis#:~:text=Symptoms%20of%20psoriasis%20vary%20from,Thick%2C%20ridged%2C%20pitted%20nails. Accessed on September 2024.
7. National Psoriasis Foundation. https://www.psoriasis.org/content/statistics. Accessed on September 2024.
8. BIMZELX® (bimekizumab) EU SmPC. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Accessed on September 2024.

GL-BK-2400101
Date of preparation: September 2024