

## **New BIMZELX® ▼ (bimekizumab) two-year data in moderate to severe plaque psoriasis presented at the 30<sup>th</sup> European Academy of Dermatology and Venereology (EADV) Congress**

- Interim results from the BE BRIGHT open-label extension study showed clinical responses observed in bimekizumab-treated patients during the first 16 weeks of BE SURE were sustained through to two years of treatment with continuous maintenance dosing\*
- Clinical responses observed in patients switching from adalimumab to bimekizumab were also sustained through to two years, with response rates similar to patients receiving bimekizumab from baseline
- Switching from ustekinumab to bimekizumab in the open-label extension study showed sustained improvements in PASI 100 up to week 100
- Analysis of pooled safety data from up to two years of treatment in Phase 2 and 3 clinical trials showed bimekizumab was generally well tolerated with no new safety signals identified over two years

**Brussels, Belgium – 29<sup>th</sup> September 2021 – 07:30 CEST** – UCB, a global biopharmaceutical company, today announced new interim results from the BE BRIGHT open-label extension (OLE) study evaluating the long-term safety, tolerability and efficacy of BIMZELX® (bimekizumab) through to two years in adult patients with moderate to severe plaque psoriasis who completed one of the three Phase 3 pivotal studies. These data, together with additional findings from the Phase 3/3b clinical program for bimekizumab in psoriasis, were presented today across nine UCB-supported abstracts at the 30<sup>th</sup> European Academy of Dermatology and Venereology (EADV) Congress.

Bimekizumab is the first selective IL-17A and IL-17F inhibitor to be approved in the European Union for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.<sup>1</sup>

“Following the recent approval of bimekizumab in Europe, we are pleased to share new two-year data at EADV supporting the clinical value of bimekizumab in the treatment of moderate to severe psoriasis. The range of longer-term efficacy and safety data presented offer important new insights for the dermatology community and reflect our commitment to improving the standard of care for people with psoriasis,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

Interim data from the BE BRIGHT study presented at EADV showed that patients treated with bimekizumab achieved sustained levels of skin clearance (PASI 90 and PASI 100) through to two years with continuous maintenance dosing\*, and that bimekizumab was generally well tolerated, with no new safety signals identified.<sup>2,3,4</sup> Switching to bimekizumab following 24 weeks of adalimumab treatment (BE SURE) resulted in a sustained increase in PASI 90 and PASI 100 responder rates up to two years.<sup>2,5</sup> In addition, switching to bimekizumab following 52 weeks of ustekinumab treatment (BE VIVID) resulted in a sustained increase in PASI 100 responder rates up to week 100.<sup>3,6</sup> Patients switching to bimekizumab after an inadequate response to ustekinumab at week 52 also showed sustained improvements in levels of skin clearance (PASI 90 and PASI 100).<sup>3</sup>

“In clinical practice, patients with moderate to severe plaque psoriasis may need to transition between biologics to optimally control their disease. Longer-term results from the BE SURE study and the BE BRIGHT open-label extension study shared at EADV 2021 demonstrated that switching from adalimumab to bimekizumab helped more patients with moderate to severe psoriasis to achieve and maintain completely clear skin, as measured by PASI 100, through two years of treatment,” said Professor Diamant Thaçi, Institute and Comprehensive Center for Inflammation Medicine, University Hospital of Lübeck, Lübeck, Germany.

### ***Longer-term results from BE SURE and BE BRIGHT open-label extension trials\****

After completing the phase 3 BE SURE trial, patients could enrol in the OLE study.<sup>2,5</sup> In bimekizumab-randomized patients (320 mg every four weeks [Q4W] through two years), PASI 90 response rates were 91.2 percent at both weeks 16 and 104.<sup>2,5</sup> PASI 100 response rates in this group were 61.6 percent at week 16 and 72.3 percent at week 104.<sup>2,5</sup> In bimekizumab-randomized patients (320 mg Q4W for 16 weeks, and then every eight weeks [Q8W] through two years), the percentage of patients reaching PASI 90 was 89.4 percent at week 16 and 89.7 percent at week 104.<sup>2,5</sup> Levels of PASI 100 response in this group were 62.8 percent at week 16 and 68.1 percent at week 104.<sup>2,5</sup>

Switching from adalimumab to bimekizumab 320 mg Q4W resulted in sustained response rates (PASI 90 and PASI 100) through to two years (week 104), which were comparable to the response rates seen in patients receiving continuous bimekizumab treatment.<sup>2</sup> Bimekizumab was well tolerated over two years, with no new safety signals.<sup>2</sup>

### ***Bimekizumab data up to two years in patients switching from ustekinumab<sup>‡</sup>***

This analysis included adult patients from BE VIVID who were initially randomized to ustekinumab 45 mg / 90 mg (by weight) at weeks 0 / four, then every 12 weeks, or bimekizumab 320 mg Q4W through week 52.<sup>3,6</sup> Based on the PASI 90 response at week 52, patients entering the OLE were re-randomized to bimekizumab 320 mg Q4W or Q8W.<sup>3</sup>

At entry to the OLE study, 44.9 percent of ustekinumab-treated patients and 73.6 percent of bimekizumab-treated patients had achieved PASI 100.<sup>3</sup> For all patients who switched from ustekinumab to bimekizumab the PASI 100 response increased to 65.4 percent at week 56, 78.7 percent at week 68 and 69.9 percent at week 100, which was comparable to the response rate seen in patients receiving continuous bimekizumab treatment at week 68 (75.4 percent) through week 100 (68.8 percent).<sup>3</sup> For patients who switched to bimekizumab following an inadequate response to ustekinumab at week 52, high levels of response were achieved. At week 56, after one dose of bimekizumab, 77.3 percent of these patients achieved PASI 90 and 40.9 percent achieved PASI 100. These responses were sustained and further improved at week 100, with 84.1 percent and 54.5 percent of patients achieving PASI 90 and PASI 100, respectively. There were no unexpected safety findings in patients who switched from ustekinumab to bimekizumab during the OLE.<sup>3</sup>

### ***Pooled safety data from up to two years of treatment in Phase 2 and 3 clinical trials***

Across Phase 2 and 3 trials, the total bimekizumab exposure was 3109.7 patient-years (N=1789).<sup>4</sup> Treatment emergent adverse events (TEAEs) occurred at an exposure-adjusted incidence rate (EAIR) of 202.4 per 100 patient-years, serious TEAEs were seen at an EAIR of 5.9 new cases per 100 patient-years and TEAEs leading to discontinuation at 3.8 new cases per 100 patient-years.<sup>4</sup> The most common TEAEs in the Phase 2 and 3 trials with bimekizumab were nasopharyngitis (EAIR: 19.1 new cases per 100 patient-years), oral candidiasis (12.6 new cases per 100 patient-years) and upper respiratory tract infection (8.9 new cases per 100 patient-years).<sup>4</sup> The EAIR for oral candidiasis showed a decrease compared with one year of bimekizumab treatment (12.6 new cases per 100 patient-years versus 16.4 new cases per 100 patient-years) and was lower with bimekizumab dosed Q8W (9.6 per 100 patient-years) compared with Q4W (16.4 per 100 patient-years).<sup>4</sup> The majority of cases (98.5 percent of patients experiencing oral candidiasis) were mild or moderate and rarely led to study discontinuation.<sup>4</sup>

*\*The recommended bimekizumab dose for adult patients with plaque psoriasis is 320 mg (given as two subcutaneous injections of 160 mg) at week 0, four, eight, 12, 16 and every eight weeks thereafter.<sup>1</sup> For some patients with a body weight  $\geq 120$  kg who did not achieve complete skin clearance at week 16, 320 mg every four weeks after week 16 may further improve treatment response.<sup>1</sup> In the studies reported at EADV 2021, patients received maintenance dosing of bimekizumab 320 mg Q4W or Q8W.*

*‡ Modified non-responder imputation analyses*

*‡ Non-responder imputation analyses*

### **About BE BRIGHT<sup>7</sup>**

BE BRIGHT (NCT03598790) is an ongoing, multicentre, open-label extension study assessing the long-term safety, tolerability and efficacy of bimekizumab in adult patients with moderate to severe plaque psoriasis. Patients who completed one of three bimekizumab Phase 3 studies, BE READY, BE VIVID and BE SURE, were eligible to enroll in the BE BRIGHT study. More details can be found at [ClinicalTrials.gov](https://clinicaltrials.gov).

### **About BIMZELX (bimekizumab) in the EU**

Bimekizumab is a humanized IgG1 monoclonal antibody that selectively binds with high affinity to IL-17A, IL-17F and IL-17AF cytokines, blocking their interaction with the IL-17RA/IL-17RC receptor complex.<sup>1</sup> Elevated concentrations of IL-17A and IL-17F have been implicated in the pathogenesis of several immune-mediated

inflammatory diseases including plaque psoriasis.<sup>1</sup> Bimekizumab inhibits these proinflammatory cytokines, resulting in the normalization of skin inflammation and as a consequence improvement in clinical symptoms associated with psoriasis.<sup>1</sup>

### **Bimzelx® ▼ (bimekizumab) EU/EEA\* Important Safety Information**

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 ( $\geq 1/100$  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, fatigue. Elderly may be more likely to experience certain adverse reactions such as oral candidiasis, dermatitis and eczema when using bimekizumab.

\*EU/EEA means European Union/European Economic Area

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. [https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf)

European summary of product characteristics date of revision August 2021

Last accessed: September 2021.

▼ *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*

### **About UCB**

UCB, Brussels, Belgium ([www.ucb.com](http://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 8,400 people in nearly 40 countries, the company generated revenue of €5.3 billion in 2020. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB\_news.

**Forward looking statements UCB**

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: the global spread and impact of COVID-19, 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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**For further information, contact UCB:**

**Corporate Communications**

Laurent Schots,  
Media Relations, UCB  
T +32.2.559.92.64  
laurent.schots@ucb.com

**Investor Relations**

Antje Witte,  
Investor Relations, UCB  
T +32.2.559.94.14  
antje.witte@ucb.com

**Brand Communications**

Eimear O'Brien,  
Brand Communications, UCB  
T +32.2.559.92.71  
eimear.obrien@ucb.com

**References**

- <sup>1</sup> BIMZELX (bimekizumab) EU Summary of Product Characteristics, August 2021. [https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf).
- <sup>2</sup> Thaçi D, Vender R, de Rie M, et al. Safety and efficacy of bimekizumab through 2 years in patients with moderate to severe plaque psoriasis: Longer-term results from the BE SURE randomised controlled trial and the BE BRIGHT open-label extension trial. Presented at EADV 2021.
- <sup>3</sup> Leonardi C, Sator PG, Morita A, et al. Bimekizumab efficacy and safety up to two years in patients with moderate to severe plaque psoriasis switching from ustekinumab: Interim results from the BE BRIGHT open-label extension trial. Presented at EADV 2021.
- <sup>4</sup> Reich K, Stähle M, Okubo Y, et al. Bimekizumab safety in patients with moderate to severe plaque psoriasis: Analysis of pooled data from up to two years of treatment in phase 2 and 3 clinical trials. Presented at EADV 2021.
- <sup>5</sup> Warren RB, Blauvelt A, Bagel J, et al. Bimekizumab versus Adalimumab in Plaque Psoriasis. *N Engl J Med.* 2021;385(2):130-141.
- <sup>6</sup> Reich K, Papp KA, Blauvelt A, et al. Bimekizumab versus ustekinumab for the treatment of moderate to severe plaque psoriasis (BE VIVID): efficacy and safety from a 52-week, multicentre, double-blind, active comparator and placebo-controlled phase 3 trial. *Lancet.* 2021;397(10273):487-498.
- <sup>7</sup> ClinicalTrials.gov. A Study to Evaluate the Efficacy and Safety of Bimekizumab in Adult Subjects With Moderate to Severe Chronic Plaque Psoriasis (BE BRIGHT). Available at: <https://clinicaltrials.gov/ct2/show/NCT03598790?term=NCT03598790&draw=2&rank=1>. Last accessed September 2021.