



## ***The Lancet* Publishes Results from Two Bimekizumab Phase 3 Studies in Psoriatic Arthritis**

- Two articles report results from the Phase 3 BE OPTIMAL and BE COMPLETE studies evaluating bimekizumab, a selective inhibitor of IL-17A and IL-17F, in patients with psoriatic arthritis

**Brussels (Belgium), 7th December 2022 – 07:00 (CET)** – UCB, a global biopharmaceutical company, today announced that *The Lancet* has published two articles detailing 24-week results from the Phase 3 BE OPTIMAL study and 16-week results from the Phase 3 BE COMPLETE study, evaluating the efficacy and safety of bimekizumab in the treatment of adults with active psoriatic arthritis who were biologic-naïve and tumour necrosis factor inhibitor inadequate responders (TNFi-IR), respectively.<sup>1,2</sup>

“Publication of two articles in tandem in *The Lancet*, one of the world’s most prestigious peer-reviewed journals, highlights the significance of these Phase 3 bimekizumab studies to the medical community. We look forward to continuing to work with regulatory agencies to make bimekizumab available to people living with psoriatic arthritis as soon as possible,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of US, UCB.

Data from BE OPTIMAL and BE COMPLETE show that both studies met their primary and all ranked secondary endpoints.<sup>1,2</sup> A significantly higher proportion of patients treated with bimekizumab achieved improvements in joint symptoms at week 16 compared with placebo – as measured by ACR50, the primary endpoint – with a consistent clinical response observed in both biologic-naïve and TNFi-IR populations ( $p < 0.0001$  for each). In addition, at week 16, a significantly higher proportion of bimekizumab-treated patients compared with placebo achieved high levels of skin clearance – as measured by PASI 90, a secondary endpoint – with a consistent clinical response in both populations ( $p < 0.0001$  for each). The safety profile of bimekizumab was consistent with safety data seen in previous studies with no new observed safety signals.<sup>1,2</sup>

In September 2022, UCB announced that the European Medicines Agency had accepted the marketing authorization application for [bimekizumab for the treatment of active psoriatic arthritis in adults](#).

The efficacy and safety of bimekizumab in the treatment of psoriatic arthritis have not been established and it is not approved for the treatment of psoriatic arthritis by any regulatory authority worldwide.

### **Notes to editors:**

#### **About BE OPTIMAL**

BE OPTIMAL was a randomized, multicenter, double-blind, placebo-controlled, active reference (adalimumab), parallel-group, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in the treatment of adult patients with active psoriatic arthritis, who are biologic disease-modifying anti-rheumatic drug naïve. For additional details on the study, see article in *The Lancet*.<sup>1</sup>





## About BE COMPLETE

BE COMPLETE was a randomized, multicenter, double-blind, placebo-controlled, parallel-group, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in adults with active psoriatic arthritis and an inadequate response to tumor necrosis factor-alpha inhibitors (TNF $\alpha$ i).<sup>2</sup> All enrolled study participants had a history of inadequate response (lack of efficacy after at least three months of therapy at an approved dose) or intolerance to treatment with one or two TNF $\alpha$ i for either psoriatic arthritis or psoriasis. For additional details on the study, see article in *The Lancet*.<sup>2</sup>

## 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.<sup>3</sup> 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).<sup>4</sup>

## 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.<sup>5,6</sup> In August 2021, bimekizumab was 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.<sup>6,7</sup> The label information may differ in other countries. Please check local prescribing information.

## About BIMZELX<sup>®</sup> ▼ (bimekizumab) in the EU/EEA

In the EU/ EEA, BIMZELX<sup>®</sup> is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.<sup>6</sup>

## BIMZELX<sup>®</sup> ▼ (bimekizumab) EU/EEA Important Safety Information in Psoriasis<sup>6</sup>

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 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. [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)

EU summary of product characteristics date of revision May 2022

Last accessed: December 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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##### 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 8,600 people in approximately 40 countries, the company generated revenue of €5.8 billion in 2021. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB\_news.

##### 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





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Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

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