UCB News

New Three-Year BIMZELX®▼ (bimekizumab) Data Reinforce Long-Term Maintenance of Complete Skin Clearance in Moderate to Severe Plaque Psoriasis

- Three-year data from the BE BRIGHT open-label extension study are being presented at the 31st EADV Congress
- Over eight out of 10 patients who achieved complete skin clearance (PASI 100) at week 16 maintained PASI 100 responses and health-related quality of life outcomes through to three years
- Analysis of pooled safety data from up to three years of treatment in Phase 2 and 3 clinical trials showed bimekizumab was generally well tolerated with no new safety signals identified over three years

Brussels (Belgium), 7th September 2022 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced new three-year results from the BE BRIGHT open-label extension (OLE) study evaluating the long-term safety, tolerability and efficacy of BIMZELX® (bimekizumab) in adults with moderate to severe plaque psoriasis who completed one of three pivotal Phase 3 studies.[1] These data, together with a three-year safety analysis of pooled data from Phase 2 and Phase 3 studies[2] are being presented at the 31st European Academy of Dermatology and Venereology (EADV) Congress in Milan, Italy, September 7–10. A total of eleven abstracts highlighting data related to bimekizumab in psoriasis are being presented at the 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.[3]

Data presented from the BE BRIGHT OLE study showed that over eight out of 10 patients who achieved complete skin clearance (PASI 100) following 16 weeks of bimekizumab treatment maintained PASI 100 response and health-related quality of life outcomes through to three years with continuous maintenance dosing.* In addition, approximately nine out of 10 patients who achieved absolute PASI (PASI ≤2) at week 16 maintained this response through to three years.[1] Pooled data from up to three years of treatment in Phase 2 and 3 clinical trials showed that bimekizumab was generally well-tolerated over this period with no safety signals identified.[2]

"These positive results highlight the deep and long-lasting skin clearance achieved with bimekizumab, along with a consistent safety and tolerability profile, and reinforce the positive

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relationship clearing skin has on patients' quality of life. These new data add to the growing body of evidence supporting longer-term use of bimekizumab in moderate to severe plaque psoriasis," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

"The findings presented today show that bimekizumab provided maintenance of completely clear skin and health-related quality of life outcomes in the majority of patients with moderate to severe plaque psoriasis over a three-year period," said Dr Bruce Strober, Clinical Professor of Dermatology at Yale University, Connecticut, U.S. "The goal of psoriasis treatment often is complete clearance of skin symptoms and the availability of long-term data across treatment options is important since it supports healthcare providers and patients to be more informed when making treatment decisions."

Three-year data from the BE BRIGHT OLE study

All patients who had completed one of the pivotal Phase 3 studies (BE SURE, BE VIVID and BE READY) were eligible to enter the BE BRIGHT OLE study.[1] On OLE entry, patients were assigned to bimekizumab 320 mg every four weeks (Q4W) or every eight weeks (Q8W) based on PASI 90 response at the end of the respective Phase 3 study.

In all bimekizumab-randomized patients:[1¥]

- Among week 16 PASI 100 responders (N=503), 89.3 percent achieved PASI 100 at year one (week 52) and 82.0 percent at year three (OLE week 96)
- Among week 16 PASI ≤2 responders (N=694), 96.5 percent achieved PASI ≤2 at year one (week 52) and 94.2 percent at year three (OLE week 96)
- Among week 16 PASI 100 responders in BE SURE and BE READY only (N=330), 92.0 percent achieved the Dermatology Life Quality Index (DLQI) 0/1 at year one (week 56), and 88.0 percent at year three (OLE week 96)

In bimekizumab-randomized patients (320 mg Q4W for 16 weeks, and then every eight weeks [Q8W] through three years, BE SURE and BE READY only):[1¥]

- Among week 16 PASI 100 responders (N=147), 93.6 percent achieved PASI 100 at year one (week 52) and 84.4 percent at year three (OLE week 96)
- Among week 16 PASI ≤2 responders (N=189), 98.9 percent achieved PASI ≤2 at year one (week 52) and 96.8 percent at year three (OLE week 96)
- Among week 16 PASI 100 responders (N=147), 95.8 percent achieved DLQI 0/1 at year one (week 56) and 92.5 percent at year three (OLE week 96)

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Pooled safety data from up to three years of treatment in Phase 2 and 3 clinical trials
Total bimekizumab exposure was 4245.3 patient-years (PY; N=1789) across the Phase 2 and 3 trials, and 3876.4 PY (N=1495; Q4W: 1965.6 PY; Q8W: 1914.5 PY) in the Phase 3 trials.[2] Treatment emergent adverse events (TEAEs) occurred at an exposure-adjusted incidence rate (EAIR) of 186.1 per 100 PY, serious TEAEs were seen at an EAIR of 5.6 new cases per 100 PY and TEAEs leading to discontinuation at 3.5 new cases per 100 PY.[2]

The most common TEAEs in the Phase 2 and 3 trials with bimekizumab were nasopharyngitis, oral candidiasis and upper respiratory tract infection at EAIRs of 15.3, 10.2 and 7.1 new cases per 100 PY, respectively.[2] The EAIR for oral candidiasis showed a decrease compared with two years of bimekizumab treatment (10.2 versus 12.6 new cases per 100 PY) and was lower with bimekizumab dosed Q8W compared with Q4W (7.1 and 15.9 per 100 PY, respectively).[2] The vast majority of oral candidiasis events were mild to moderate (99.4 percent) and none were serious.[2] Serious infections occurred at a rate of 1.2/100 PY. The most frequently reported were serious coronavirus infections (0.2 per 100 PY).[2]

** The recommended bimekizumab dose for adult patients with plaque psoriasis is 320 mg (given as two subcutaneous injections of 160 mg) at week 0, 4, 8, 12, 16 and every eight weeks thereafter.[3] For some patients with a body weight≥120 kg who did not achieve complete skin clearance at week 16, 320 mg every 4 weeks after week 16 may further improve treatment response.[3] In the studies reported at EADV 2022, patients received maintenance dosing of bimekizumab 320 mg Q4W or Q8W.*

¥ Modified non-responder imputation analyses

Notes to editors :

About BE BRIGHT

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 chronic plaque psoriasis.[4] Patients who completed one of three bimekizumab Phase 3 studies, BE READY, BE VIVID and BE SURE, were eligible to enrol in the BE BRIGHT study.[4] More details on BE BRIGHT can be found at ClinicalTrials.gov.[4]

BE VIVID, BE READY and BE SURE evaluated the efficacy and safety of bimekizumab in the treatment of adults with moderate to severe plaque psoriasis versus placebo and ustekinumab, versus placebo, and versus adalimumab, respectively.[5,6,7]

About psoriasis

Psoriasis is a chronic inflammatory disease with primary involvement of the skin.[8] Psoriasis signs and symptoms can vary but may include red patches of skin covered with silvery scales; dry, cracked skin that may bleed; and thickened, pitted or ridged nails.[9] Psoriasis also has a considerable psychological and quality-of-life impact, potentially affecting work, recreation, relationships, sexual functioning, family and social life.[10] This skin condition affects men and women of all ages and ethnicities.[8]

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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.[3,11]

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[3,12] The label information may differ in other countries. Please check local prescribing information.

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, 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

EU summary of product characteristics date of revision March 2022.

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▼ *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) 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.

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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

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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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