UCB News

New Long-Term Complete Skin Clearance Data for BIMZELX®▼ (bimekizumab) in Moderate to Severe Plaque Psoriasis Presented at the 2022 AAD Annual Meeting

- Eleven abstracts highlight new data on bimekizumab in the treatment of adults with moderate to severe plaque psoriasis
- Pooled data from five Phase 3/3b trials showed that more than eight out of 10 patients who achieved complete skin clearance with bimekizumab at week 16, and entered open-label extension, maintained this response through two years
- Data from the open-label extension period of the BE RADIANT study showed that complete skin clearance achieved at week 48 was maintained through week 96 with continuous bimekizumab treatment and improved for patients who switched from secukinumab to bimekizumab

Brussels (Belgium), 26th March 2022 – 15:30 CEST – UCB, a global biopharmaceutical company, today announced that it is presenting 11 abstracts on bimekizumab in the treatment of adults with moderate to severe plaque psoriasis at the 2022 American Academy of Dermatology (AAD) Annual Meeting in Boston, Massachusetts, U.S., on March 25-29, including a late breaking oral platform presentation and 10 posters. The platform presentation details new analysis of pooled data from five bimekizumab Phase 3/3b clinical trials, which showed that over 80 percent of patients who achieved complete skin clearance (PASI100) at week 16 and entered the open-label extension (OLE) studies maintained this response through two years follow up, and no new safety signals were identified.[1]

Among the poster presentations, new data from the OLE period of the Phase 3b BE RADIANT study showed that clinical responses (PASI100 and absolute PASI, PASI ≤2) achieved at week 48 were maintained through week 96 with continuous treatment with bimekizumab and improved for patients who switched from secukinumab to bimekizumab on entry to the OLE.[2,3] Patients who were PASI90 non-responders with secukinumab at week 48 achieved improved clinical responses (PASI90 and PASI100) after switching to bimekizumab in the OLE.[3] Among patients who were PASI90 responders with secukinumab at week 48, PASI90 response was maintained and PASI100 response increased following switch to bimekizumab in the OLE.[3]

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In the European Union and Great Britain, bimekizumab is the first selective IL-17A and IL-17F inhibitor to be approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[4,5] Bimekizumab is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe plaque psoriasis in adults.

"Long term complete skin clearance is an important goal for people with psoriasis, and the new 96-week data from the open-label extension period of the BE RADIANT study offer fresh insights on the sustained response and clinical potential of bimekizumab in moderate to severe plaque psoriasis," said Bruce Strober, M.D., Ph.D., Clinical Professor, Department of Dermatology, Yale University School of Medicine, New Haven, CT, U.S., and Central Connecticut Dermatology Research, Cromwell, CT, U.S. "In addition, the improved clinical responses seen in patients who switched to bimekizumab after 48 weeks of treatment with secukinumab offer further new insights that should help to inform future clinical practice."

Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB, said: "We are pleased to share our latest long-term data on bimekizumab with the dermatology community at the 2022 AAD Annual Meeting. The wealth of new data, insights and progress being presented underlines our commitment to advances in psoriasis care for people living with this challenging, life-long condition."

Phase 3/3b studies: two-year pooled data for bimekizumab in patients with moderate to severe plaque psoriasis[1]
Data were pooled from the BE VIVID, BE READY, and BE SURE Phase 3 trials, the Phase 3b BE RADIANT trial and OLE (48 weeks), and the first year of the BE BRIGHT OLE study. Analysis evaluated PASI100 maintenance through two years (OLE 48 weeks) among PASI100 week 16 responders who entered the respective OLE studies and received continuous bimekizumab maintenance dosing from week 16 (320 mg every four weeks [Q4W/Q4W/Q4W] or Q4W/Q8W/Q8W*). At week 16, 62.4 percent of bimekizumab-treated patients (n=850) achieved PASI100. Of those who entered the OLEs, 85.1 percent (Q4W/Q4W/Q4W; n=316) and 83.8 percent (Q4W/Q8W/Q8W*; n=267) maintained PASI100 at year two (OLE week 48). The exposure-adjusted incidence rates (EAIRs) of overall and serious treatment emergent adverse events (TEAEs) were 192.7 and 5.9. The most common TEAEs were nasopharyngitis (EAIR of 18.4), oral candidiasis (13.0) and upper respiratory tract infections (7.8). Almost all cases of oral candidiasis (98.1 percent) were mild or moderate.

BE RADIANT open-label extension study in patients with moderate to severe plaque psoriasis: efficacy and safety data through 96 weeks[2]
Complete skin clearance (PASI100) levels observed with bimekizumab in the BE RADIANT study were maintained in the OLE through week 96 (74.8 percent and 70.6 percent at weeks 48 and 96, respectively) and improved for patients who switched from secukinumab to bimekizumab on entry to the OLE period (52.8 percent and 76.1 percent at weeks 48 and 96, respectively). The absolute PASI response (PASI≤2) was also maintained through week 96 (94.3 percent and 93.4 percent at weeks

48 and 96, respectively) and improved for patients who switched from secukinumab to bimekizumab on entry to the OLE period (83.9 percent and 94.6 percent at weeks 48 and 96, respectively). During the OLE, the most common adverse events with bimekizumab were nasopharyngitis (11.8/100 patient-years), oral candidiasis (7.8/100 patient-years), and urinary tract infection (4.5/100 patient-years). Adverse events were comparable between patients continuing bimekizumab or switching from secukinumab to bimekizumab. The incidence of serious adverse events was low. These analyses included 336 patients treated with bimekizumab, and 318 patients treated with secukinumab who completed the BE RADIANT double-blinded period and entered the OLE.

BE RADIANT open-label extension study in patients with moderate to severe plaque psoriasis: responder analysis in patients switching from secukinumab to bimekizumab[3]
At week 48, 53/318 patients (16.7 percent) treated with secukinumab had not achieved PASI90. After switching to bimekizumab in the OLE, responses improved. At week 96, 79.2 percent of this group achieved PASI90 and 50.9 percent achieved PASI100. At week 48, 256/318 patients (80.5 percent) treated with secukinumab had achieved PASI90. After switching to bimekizumab in the OLE, 95.2 percent of this group maintained this response at week 96 and the PASI100 response increased from 65.2 percent at week 48 to 79.9 percent at week 96. No clinically relevant differences in safety outcomes for patients who switched from secukinumab to bimekizumab were observed from weeks 48-96.

**In the EU 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. For some patients with a body weight ≥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[4]*

¥ Modified non-responder imputation analyses

About the BE READY, BE VIVID and BE SURE studies and the BE BRIGHT open-label extension study[6,7,8,9]

The efficacy and safety of bimekizumab in the treatment of adults with moderate to severe plaque psoriasis were evaluated in three Phase 3 studies, versus placebo and ustekinumab (BE VIVID), versus placebo (BE READY) and versus adalimumab (BE SURE). Patients who completed one of these three Phase 3 studies were eligible to enroll in the BE BRIGHT open-label extension study.

About the BE RADIANT and BE RADIANT open-label extension study[10]

BE RADIANT was a Phase 3b, randomized, multicenter, double-blind, active comparator-controlled, parallel-group study designed to assess the efficacy and safety of bimekizumab compared to secukinumab in adults with moderate to severe chronic plaque psoriasis. Patients who completed the

48-week double-blinded period were able to enroll in the ongoing 96-week open-label extension, where they all received bimekizumab.

About BIMZELX® (bimekizumab)

Bimekizumab is a humanized monoclonal IgG1 antibody that is designed to selectively and directly inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), two key cytokines driving inflammatory processes.[11]

About BIMZELX® ▼ in the EU/EEA*

In the EU, BIMZELX® is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[4]

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 (≥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.

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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 August 2021

Last accessed: March 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) 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,

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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 ingeneral 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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