UCB Announces European Commission Approval of BIMZELX®▼(bimekizumab) for the Treatment of Adults with Moderate to Severe Plaque Psoriasis

- BIMZELX®▼(bimekizumab) is the first approved treatment for moderate to severe plaque psoriasis that is designed to selectively and directly inhibit both IL-17A and IL-17F
- The approval in the European Union represents the first marketing authorization for UCB's new psoriasis treatment worldwide
- Approval is supported by three Phase 3 trials where bimekizumab demonstrated superior levels of skin clearance compared to placebo, ustekinumab and adalimumab, and was generally well-tolerated
- Bimekizumab is testament to UCB's commitment to advancing science in immuno-dermatology, addressing unmet needs and improving patient outcomes

Brussels, Belgium – 24th August 2021 – 07:00 CEST - UCB, a global biopharmaceutical company, today announced that the European Commission (EC) has granted marketing authorization for BIMZELX® (bimekizumab) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[1] Bimekizumab is the first approved treatment in the European Union (EU) for moderate to severe plaque psoriasis that is designed to selectively and directly inhibit both IL-17A and IL-17F, two key cytokines driving inflammatory processes.[1]

Bimekizumab is approved at a recommended dose of 320 mg, administered by two subcutaneous injections every four weeks to week 16 and every eight weeks thereafter.[1] 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.[1]

"The approval of BIMZELX in Europe is the first marketing authorization for this new psoriasis treatment worldwide and represents a landmark moment for the dermatology community and UCB. Our ambition is to transform the lives of people living with severe diseases, and we are incredibly proud to bring a new treatment option to people living with moderate to severe plaque psoriasis in Europe. We believe that bimekizumab has the potential to raise expectations of what psoriasis treatment can deliver." said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of US, UCB.

Psoriasis can have a considerable physical and psychological impact on patients, as well as being detrimental to their quality of life, potentially affecting work, recreation, relationships, family and social life.[2] A cross-sectional patient survey showed at least 90 percent of patients with moderate to severe plaque psoriasis place a high value on treatment which provides clear skin, a sustained response and rapid onset of action.[3] In addition, a real-world study showed that gaining completely clear skin can make a meaningful difference to the impact psoriasis has on patients' health-related quality of life.[4]

"In the pivotal Phase 3 studies patients treated with bimekizumab achieved superior levels of skin clearance compared to those treated with placebo, adalimumab and ustekinumab, and in the Phase 3b study, treatment with bimekizumab resulted in greater levels of skin clearance than secukinumab. Across studies, about 60 percent of bimekizumab-treated patients achieved complete skin clearance at week 16, and this response was maintained for up to a year." said Professor Richard Warren, Salford Royal NHS Foundation Trust and The University of Manchester, UK. "The approval of bimekizumab in the EU provides a welcome new treatment option that may help more patients with moderate to severe plaque psoriasis to achieve their treatment goals."

The European Commission approval follows a positive opinion granted in June 2021 by the European Medicines Agency's Committee for Medicinal Products for Human Use. The approval is supported by positive results from three Phase 3 studies, which evaluated the efficacy and safety of bimekizumab in 1,480 patients with moderate to severe plaque psoriasis.[1] Full findings from the Phase 3 BE READY and BE VIVID studies are published in *The Lancet*, and the results of the Phase 3 BE SURE study are published in *The New England Journal of Medicine.*[5,6,7]

The approval from the European Commission is valid in all 27 member states of the EU, as well as Iceland, Liechtenstein, and Norway. Bimekizumab is currently under review by the U.S. Food & Drug Administration (FDA) for the treatment of adults with moderate to severe plaque psoriasis. Regulatory reviews are also underway in Australia, Canada, Great Britain and Japan.

Notes to Editors:

About the Phase 3 Psoriasis Clinical Development Program
The efficacy and safety of bimekizumab were evaluated in three Phase 3 studies, versus placebo and ustekinumab (BE VIVID), versus placebo (BE READY) and versus adalimumab (BE SURE).[5,6,7] All studies met their co-primary endpoints and all ranked secondary endpoints.[5,6,7]

Patients treated with bimekizumab achieved superior levels of skin clearance at week 16, compared to those who received ustekinumab (ranked secondary endpoint, BE VIVID; $p<0.0001$), placebo (co-primary endpoint, BE READY and BE VIVID; $p<0.0001$) and adalimumab (co-primary endpoint, BE SURE; $p<0.001$), as measured by at least a 90 percent improvement in the Psoriasis Area & Severity Index (PASI 90) and an Investigator's Global Assessment (IGA) response of clear or almost clear skin (IGA 0/1).[5,6,7] Clinical responses achieved with bimekizumab at week 16 were maintained up to one year in all studies.[5,6,7] The most frequently reported adverse reactions in the clinical studies were upper respiratory tract infections (14.5 percent) (most frequently nasopharyngitis) and oral candidiasis (7.3 percent).[1] For additional information on the bimekizumab Phase 3 clinical trial program, in psoriasis, please refer to the peer-reviewed publications and visit www.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.[1] Elevated concentrations of IL-17A and IL-17F have been implicated in the pathogenesis of several immune-mediated inflammatory diseases including plaque psoriasis.[1] Bimekizumab inhibits these proinflammatory cytokines, resulting in the normalization of skin inflammation and as a consequence improvement in clinical symptoms associated with psoriasis.[1]

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. 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

▼ *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) 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’ 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.

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.

UCB is providing this information, including forward-looking statements, only as of the date of this press release and it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated otherwise. UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. UCB expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

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