BIMZELX® (bimekizumab) Approved in Japan for the Treatment of Plaque Psoriasis, Generalized Pustular Psoriasis and Psoriatic Erythroderma

- The third approval for bimekizumab worldwide reinforces UCB's commitment to bring new treatment options to the global dermatology community
- Approval is supported by positive results from Phase 3/3b clinical studies which evaluated bimekizumab versus placebo and three commonly used biologics, ustekinumab, adalimumab and secukinumab

Brussels, Belgium – 24th January 2022 – 07:00 – UCB, a global biopharmaceutical company, today announced that the Japanese Ministry of Health, Labor and Welfare (MHLW) has granted marketing authorization for BIMZELX® (bimekizumab) for the treatment of plaque psoriasis, generalized pustular psoriasis and psoriatic erythroderma in patients who are not sufficiently responding to existing treatments. Bimekizumab is the first approved psoriasis treatment in Japan that is designed to selectively and directly inhibit two key cytokines driving inflammatory processes – interleukin 17F (IL-17F) and interleukin 17A (IL-17A).

This announcement marks the third approval for bimekizumab worldwide, following marketing authorization in countries of the European Union/European Economic Area and Great Britain in August 2021 for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[1,2]

"The approval of BIMZELX® in Japan is an important milestone that reinforces UCB's commitment to the dermatology community and to advancing standards of care in psoriasis," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of US, UCB. "At UCB, our ambition is to transform the lives of people living with severe diseases. We are incredibly proud to bring a new psoriasis treatment option to healthcare professionals and patients in Japan to help support more patients in reaching their treatment goals."

Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin.[3] There are several types of psoriasis, though plaque psoriasis is the most common, comprising between 58 percent and 97 percent of all cases.[4] Plaque psoriasis is characterized by dry, red plaques, usually covered with silvery or white scales.[4] Generalized pustular psoriasis is less common, affecting between 1.1 percent and 12 percent of all cases, and characterized by coalescing pustules, filled with non-infectious pus.[4] Psoriatic erythroderma is the most serious type of psoriasis characterized by fiery redness and exfoliation of most of the body surface, affecting between 0.4 percent and 7 percent of all cases.[4]

The approval in Japan is supported by the positive results from the Phase 3/3b clinical studies, BE READY, BE VIVID, BE SURE and BE RADIANT which evaluated the efficacy and safety of bimekizumab compared with placebo, ustekinumab, adalimumab and secukinumab in adults with moderate to severe plaque psoriasis, as well as results from the open-label extension study BE BRIGHT.[5,6,7,8,9] Bimekizumab demonstrated superior levels of skin clearance* compared to placebo, ustekinumab, adalimumab and secukinumab, and was generally well-tolerated.[5,6,7,8,9] Full findings from the BE READY and BE VIVID studies are published in *The Lancet*, and the results from the BE SURE and BE RADIANT studies are published in *The New England Journal of Medicine*.[5,6,7,8]

UCB is committed to bringing bimekizumab to patients worldwide. 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. Regulatory reviews are also underway in Australia, Canada and Switzerland.

**Bimekizumab was evaluated in Phase 3/3b studies versus placebo (co-primary endpoint; BE READY and BE VIVID), versus adalimumab (co-primary endpoint; BE SURE), versus ustekinumab (ranked secondary endpoint; BE VIVID) and versus secukinumab (primary endpoint; BE RADIANT).[5,6,7,8]*

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.[10]

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.[1]

*EU/EEA means European Union/European Economic Area

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.

European SmPC date of revision August 2021. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

Last accessed: January 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.*

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 more than 7 600 people in approximately 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.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.

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

[1] BIMZELX® (bimekizumab) EU Summary of Product Characteristics https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Last accessed: January 2022.

[2] BIMZELX (bimekizumab) GB Summary of Product Characteristics https://www.medicines.org.uk/emc/product/12834; https://www.medicines.org.uk/emc/product/12833. Last accessed: January 2022.

[3] National Psoriasis Foundation. About Psoriasis webpage. Available at: https://www.psoriasis.org/about-psoriasis/. Last accessed: January 2022.

[4] World Health Organization. Global report on psoriasis 2016. Available at: http://apps.who.int/iris/bitstream/handle/10665/204417/9789241565189_eng.pdf;jsessionid=8753AFAF296B0371998310C3AB7F3259?sequence=1. Last accessed: January 2022.

[5] 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.

[6] Gordon KB, Foley P, Krueger JG, et al. Bimekizumab efficacy and safety in moderate to severe plaque psoriasis (BE READY): a multicentre, double-blind, placebo-controlled, randomised withdrawal phase 3 trial. *Lancet*. 2021;397(10273):475-486.

[7] Warren RB, Blauvelt A, Bagel J, et al. Bimekizumab versus Adalimumab in Plaque Psoriasis. *N Engl J Med*. 2021;385(2):130-141.

[8] Reich K, Warren R, Lebwohl M et al. Bimekizumab versus Secukinumab in Plaque Psoriasis *N Engl J Med*. 2021;385(2):142-152.

[9] 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: January 2022.

[10] Glatt S, Helmer E, Haier B, et al. First-in-human randomized study of bimekizumab, a humanized monoclonal antibody and selective dual inhibitor of IL-17A and IL-17F, in mild psoriasis. *Br J Clin Pharmacol*. 2017;83(5):991-1001.