UCB Receives Positive CHMP Opinion Recommending Approval of BIMZELX®* (bimekizumab) in the EU for the Treatment of Adults with Moderate to Severe Plaque Psoriasis

- The positive CHMP opinion is supported by data from three Phase 3 studies where bimekizumab demonstrated superior levels of skin clearance compared to placebo, ustekinumab and adalimumab
- If approved by the European Commission, bimekizumab will be 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 European Commission is expected to deliver its decision on the marketing authorization of bimekizumab, under the trade name BIMZELX®*, in approximately two months

Brussels, Belgium – 25th June, 2021 – 11:00 AM CEST – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending granting a marketing authorization for BIMZELX®* (bimekizumab), an investigational IL-17A and IL-17F inhibitor, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

"This positive CHMP opinion is a significant regulatory milestone towards approval of bimekizumab in Europe. We're delighted by today's decision which recognizes the strength of the psoriasis clinical development program. Bimekizumab is testament to our commitment to advancing science in immuno-dermatology, addressing unmet needs and improving patient outcomes," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

The positive CHMP opinion is supported by results from three Phase 3 studies – BE VIVID, BE READY and BE SURE – which evaluated the efficacy and safety of bimekizumab in adults with moderate to severe plaque psoriasis.[1,2,3] All studies met their co-primary and all ranked secondary endpoints.[1,2,3] Patients treated with bimekizumab achieved superior levels of skin clearance (PASI 90 and IGA 0/1**) at week 16 compared to those who received adalimumab, placebo and ustekinumab.[1,2,3] Clinical responses achieved with bimekizumab at week 16 were maintained up to one year in all studies.[1,2,3] The most frequently reported treatment emergent adverse events in bimekizumab-treated patients were nasopharyngitis, oral candidiasis, and upper respiratory tract infection.[1,2,3,4]

If marketing authorization is granted by the European Commission, bimekizumab will become the first approved treatment for patients with moderate to severe plaque psoriasis in the European Union that is designed to selectively and directly inhibit both IL-17A and IL-17F, two key cytokines driving inflammatory processes.[1,2,3] The positive CHMP opinion is a scientific recommendation which is shared with the European Commission for the adoption of a decision on an EU-wide marketing authorization. A European Commission marketing authorization through the centralized procedure is valid in all European Union Member States, as well as the European Economic Area countries Iceland, Liechtenstein and Norway.

UCB is committed to bringing bimekizumab to patients worldwide. Bimekizumab is currently under review by the U.S. Food and Drug Administration for the treatment of adults with moderate to severe plaque psoriasis. Regulatory reviews are also underway in Japan, Australia and Canada. The efficacy and safety of bimekizumab are also being evaluated in Phase 3 trials in psoriatic arthritis,[5,6] ankylosing spondylitis,[7] non-radiographic axial spondyloarthritis,[8] and hidradenitis suppurativa.[9,10]

Notes to Editors:

** The proprietary name BIMZELX® has been provisionally accepted by the EMA*

*** PASI 90 - at least a 90 percent improvement in the Psoriasis Area and Severity Index; IGA 0/1 - Investigator's Global Assessment response of clear or almost clear skin.*

About Psoriasis
Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin.[11] This skin condition affects men and women of all ages and ethnicities.[11] 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.[12] Psoriasis also has a considerable psychological and quality-of-life impact, potentially affecting work, recreation, relationships, sexual functioning, family and social life.[13]

Unmet needs remain in the treatment of psoriasis. A population-based survey identified that approximately one in three psoriasis patients reported that their primary goals of therapy, including keeping symptoms under control, reducing itching and decreasing flaking, were not met with their current treatment.[14]

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’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.

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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