UCB News

UCB Provides Update on U.S. FDA Review of the Biologics License Application for Bimekizumab

Brussels (Belgium), 26th June 2023 – Time (18:30 CEST) – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, today announced that the Biologics License Application (BLA) for bimekizumab for the treatment of adults with moderate to severe plaque psoriasis remains under review with the U.S. Food & Drug Administration (FDA). UCB previously communicated the FDA action was expected in Q2, 2023. UCB now anticipates the FDA action in Q3, 2023. There are no open Information Requests from the FDA regarding the BLA for bimekizumab.

UCB is committed to ongoing collaboration with the FDA in order to bring bimekizumab to people in the U.S. living with moderate to severe plaque psoriasis as soon as possible.

Bimekizumab, an IL-17A and IL-17F inhibitor, is currently approved for moderate to severe psoriasis by 10 regulatory authorities and in 39 countries worldwide.[1-8] In June 2023, in countries of the European Union/European Economic Area, bimekizumab was approved for two additional indications – the treatment of adults with active psoriatic arthritis, and for the treatment of adults with active axial spondyloarthritis (axSpA), including non-radiographic axSpA and ankylosing spondylitis, also known as radiographic axSpA.[2]

UCB confirms its previously communicated 2023 financial guidance range.

UCB will host a UCB Investor Call on 27th June: 15:15–15:45 CEST; 09:15 am – 09:45 am EST; 14:15–14:45 BST. *Participant International Dial In: +1-412-902-6510; Participant UK/EU Dial In: +44 203 5143188.*

Notes to editors:

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.[1] In August 2021, bimekizumab▼received marketing authorization in countries of the European Union (EU)/European Economic Area (EEA) and Great Britain, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[2,3] In January 2022, bimekizumab received marketing authorization in Japan for the treatment of plaque psoriasis, generalized pustular psoriasis and psoriatic erythroderma in patients who are not sufficiently responding to existing treatments.[4] In February 2022, March 2022 and April 2023, bimekizumab received marketing authorization in Canada, Australia and Mexico, respectively, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[5,6] In July 2022, October 2022, January 2023 and May 2023 bimekizumab was approved in Saudi Arabia[7], Switzerland[8], the United Arab Emirates and Kuwait, respectively, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

In June 2023, bimekizumab was approved in countries of the EU/EEA, alone or in combination with methotrexate for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs.[2] In June 2023, bimekizumab was approved in countries of the EU/EEA, for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging who have responded inadequately or are intolerant to non-steroidal anti-

inflammatory drugs, and for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.[2]

▼ *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.*

For further information, contact UCB:

Investor Relations
Antje Witte
T +32.2.559.94.14
email antje.witte@ucb.com

Corporate Communications
Laurent Schots
T +32.2.559.92.64
email laurent.schots@ucb.com

Brand Communications
Eimear O'Brien
T +32.2.559.92.71
email eimear.obrien@ucb.com

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 8,700 people in approximately 40 countries, the company generated revenue of €5.5 billion in 2022. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

Forward looking statements
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: 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. 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.

References

1. 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.
2. BIMZELX (bimekizumab) EU SmPC. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf Accessed: June 2023.
3. BIMZELX (bimekizumab) GB SmPC. https://www.medicines.org.uk/emc/product/12834; https://www.medicines.org.uk/emc/product/12833 Accessed: June 2023.
4. Pharmaceuticals and Medical Devices Agency. https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html. Accessed: June 2023.
5. BIMZELX (bimekizumab) Canada Product Monograph. Available at: https://pdf.hres.ca/dpd_pm/00064702.PDF. Accessed: June 2023.
6. BIMZELX. Australian Prescription Medicine Decision Summaries. Available at: https://www.tga.gov.au/apm-summary/bimzelx. Accessed: June 2023.
7. Saudi Food & Drug Authority. https://www.sfda.gov.sa/sites/default/files/2023-04/Bimzelx.pdf. Last accessed: June 2023.
8. Swissmedic. Available at: https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/public-summary-swiss-par/public-summary-swiss-par-bimzelx.html. Last accessed: June 2023.