



UCB Provides Update on U.S. Regulatory Review of Bimekizumab

Brussels (Belgium), 19 September 2023 – Time (23:00 CEST) – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, today provided an update on the Biologics License Application (BLA) for bimekizumab for the treatment of adults with moderate to severe plaque psoriasis.

UCB has received the Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (FDA) following the pre-license inspection conducted in April 2023 at the Belgium manufacturing facility. The FDA has concluded that this inspection is successfully closed.

The FDA is continuing its review of the BLA for bimekizumab. The Agency has not communicated timelines required to take action on the application. At this time, UCB no longer anticipates FDA action in Q3, 2023.

UCB continues to collaborate with the FDA to advance and complete the full review of the bimekizumab BLA and its label. The next update for the bimekizumab BLA will be shared at the time of the FDA action.

UCB's previously communicated 2023 financial guidance range remains unchanged.

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 Arabia⁷, Switzerland⁸, 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 first 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 first 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.

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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 8,700 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.

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References

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