UCB News

Update on U.S. FDA Review of Biologics License Application (BLA) for bimekizumab

- The U.S. FDA has informed UCB via letter that the Agency was unable to complete review of the BLA for bimekizumab by the PDUFA date and is deferring action on the application
- The Agency cited only the inability to conduct on-site facility inspections due to travel restrictions as the reason for deferral
- UCB is committed to bringing bimekizumab to patients with moderate to severe plaque psoriasis in the U.S. as soon as possible and continues to work with the FDA to support the ongoing review

Brussels, Belgium – 16th, October, 2021 – 16:00 CEST – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has informed the Company that they were unable to complete review of the Biologics License Application (BLA) for bimekizumab for the treatment of moderate to severe plaque psoriasis by the Prescription Drug User Fee Action (PDUFA) date of October 15, 2021.

The Agency has determined that on-site inspections of the European manufacturing facilities for bimekizumab are required before the FDA can approve the application. The FDA indicated that they were unable to conduct the inspections during the current review cycle due to COVID-19 related restrictions on travel. Therefore, the FDA is deferring action on the application until the inspections can be completed. In the letter, the Agency cited only travel restrictions and its inability to complete facility inspections as the reason for the deferral. The BLA for bimekizumab remains under review.

Under FDA guidance relating to pre-approval inspections during the COVID-19 pandemic, the Agency may defer action on a pending application when a facility inspection is planned but cannot be completed by the PDUFA goal date due to COVID-related travel restrictions, provided that no deficiencies have been identified and the application otherwise satisfies the requirements for approval.[1]

“We are currently in contact with the FDA to schedule the inspections of our manufacturing facilities as soon as possible,” said Prof. Dr. Iris Loew Friedrich, Chief Medical Officer and Executive Vice President, Development UCB. “We have provided the Agency with the manufacturing schedules through the first quarter of 2022, and we are eager to assist the FDA to allow its assessment of bimekizumab to be finalized. We are committed to bringing bimekizumab to patients in the U.S. with moderate to severe plaque psoriasis as soon as possible.”

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] Bimekizumab is not approved by any other regulatory authority outside the EU/EEA and Great Britain. Regulatory reviews are underway in Australia, Canada, Switzerland and Japan.

UCB’s financial guidance for 2021 and 2025 remains unchanged.

About Psoriasis

Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin.[4] This skin condition affects men and women of all ages and ethnicities.[4] 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.[5] Psoriasis also has a considerable psychological and quality-of-life impact, potentially affecting work, recreation, relationships, sexual functioning, family and social life.[6]

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.[7]

About bimekizumab
Bimekizumab is an investigational humanized monoclonal IgG1 antibody that selectively and directly inhibits both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), two key cytokines driving inflammatory processes.[8] Selective inhibition of IL-17F in addition to IL-17A has been shown to suppress inflammation to a greater extent than IL-17A inhibition alone.[8,9]

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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