UCB News

UCB Achieves Important Regulatory Milestone for Bimekizumab

- The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have accepted marketing application submissions for bimekizumab for the treatment of adults with moderate to severe plaque psoriasis
- This accepted submission is supported by a robust data package including three Phase 3 studies which demonstrate superiority of bimekizumab to placebo, Stelara® (ustekinumab) and Humira® (adalimumab) in achieving skin clearance at week 16

Brussels, Belgium – 22th September 2020, 07:00 CEST – UCB, a global biopharmaceutical company, today announced that the FDA and EMA have accepted the Biologics License Application (BLA) and Marketing Authorization Application (MAA), respectively, for bimekizumab for the treatment of adults with moderate to severe plaque psoriasis.

"After a series of positive Phase 3 data readouts, we are delighted to announce that the U.S. FDA and EMA have accepted our applications to file bimekizumab as a potential new treatment for psoriasis. This milestone brings us one step closer to being able to offer a meaningful new treatment option for people living with this debilitating disease. UCB is committed to providing innovative solutions for people living with serious inflammatory diseases like psoriasis," said Emmanuel Caeymaex, Executive Vice President Immunology Solutions and Head of US, UCB.

The marketing application submissions for bimekizumab are based on data from a global Phase 3 clinical development program in psoriasis.[1,2,3] All Phase 3 studies met their primary endpoints, demonstrating that bimekizumab-treated patients achieved superior skin clearance, at week 16, compared to those who received placebo and Humira® (adalimumab) as measured by the Psoriasis Area and Severity Index (PASI 90) and an Investigator Global Assessment (IGA) response of clear or almost clear skin (IGA 0/1).[1,2,3]

All the Phase 3 studies met their ranked secondary endpoints.[1,2,3] Two studies demonstrated superior total skin clearance at week 16, as measured by PASI 100, confirming the superiority of bimekizumab over existing biologic treatments Stelara® (ustekinumab) and adalimumab.[2,3] Furthermore, bimekizumab was superior to placebo, ustekinumab and adalimumab in achieving rapid response, defined as PASI 75 at week 4.[1,2,3] Clinical responses were maintained up to one year in all studies.[1,2,3] The safety profile of bimekizumab continues to be consistent with earlier clinical studies with no new safety signals identified.[1,2,3,4,5,6]

The safety and efficacy of bimekizumab have not been established and it is not approved by any regulatory authority worldwide. Bimekizumab is currently also being evaluated in Phase 3 trials for potential indications in psoriatic arthritis,[7,8] ankylosing spondylitis,[9] non-radiographic axial spondyloarthritis[10] and hidradenitis suppurativa.[11,12]

About Bimekizumab

Bimekizumab is an investigational humanized monoclonal IgG1 antibody that selectively inhibits both IL-17A and IL-17F, two key cytokines driving inflammatory processes.[13] IL-17F has overlapping biology with IL-17A and drives inflammation independently to IL-17A.[14,15,16,17,18] Selective inhibition of IL-17F in addition to IL-17A suppresses inflammation to a greater extent than IL-17A inhibition alone.[17,18] The safety and efficacy of bimekizumab are being evaluated across multiple disease states as part of a robust clinical program.

About BE VIVID

BE VIVID is a randomized, 52-week, double-blind, placebo- and active-controlled study designed to assess the efficacy and safety of bimekizumab in adult patients with moderate to severe chronic plaque psoriasis.[19] BE VIVID enrolled 570 participants with chronic plaque psoriasis for at least six months prior to screening and with an affected body surface area of at least 10 percent and PASI of at least 12 and IGA score >=3 on a 5-point scale.[19]

The co-primary endpoints of the study were PASI 90 response (defined as a patient who achieves 90 percent improvement from baseline in the PASI score) at week 16, and Investigators' Global Assessment (IGA) 0 or 1 response (defined as clear or almost clear with at least a 2-category improvement relative to baseline) at week

16.[19] UCB announced topline findings from BE VIVID in October 2019. For additional details on the study, visit BE VIVID on clinicaltrials.gov.[19]

About BE READY
BE READY is a Phase 3, randomized, 56-week, double-blind, placebo-controlled study, with an initial treatment period followed by a randomized-withdrawal period, designed to assess the efficacy and safety of bimekizumab in adult patients with moderate to severe chronic plaque psoriasis.[20] BE READY enrolled 435 participants with chronic plaque psoriasis for at least six months prior to screening and with an affected body surface area of at least 10 percent and PASI of at least 12 and IGA score >=3 on a 5-point scale.[20]

The co-primary endpoints of the study were PASI 90 response (defined as a patient who achieves a 90 percent improvement in PASI) and IGA response (defined as clear or almost clear with at least a two-category improvement relative to baseline) at week 16.[20] UCB announced topline findings from BE READY in November 2019. For additional details on the study, visit BE READY on clinicaltrials.gov.[20]

About BE SURE
BE SURE is a Phase 3, randomized, double-blind study comparing bimekizumab to adalimumab in adult patients with moderate to severe chronic plaque psoriasis; the active-controlled initial treatment period of 24 weeks is followed by a dose-blind maintenance treatment period until week 56.[21] BE SURE enrolled 480 participants with chronic plaque psoriasis for at least six months prior to screening and with an affected body surface area of at least 10 percent, PASI of at least 12 and IGA score equal to or greater than three on a five-point scale.[21]

The co-primary endpoints of the study were PASI 90 response (defined as a patient who achieves a 90 percent improvement in PASI) and IGA response (defined as clear or almost clear with at least a two-category improvement relative to baseline) at week 16.[21] For additional details on the study, visit BE SURE on clinicaltrials.gov.[21] UCB announced topline findings from BE SURE in December 2019. For additional details, visit: BE SURE on UCB.com.

Humira® is a registered trademark of AbbVie, Inc; Stelara® is a registered trademark of Johnson & Johnson.

About Psoriasis
Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin. This skin condition affects men and women of all ages and ethnicities.[22] 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.[23]

Psoriasis affects nearly three percent of the population, or about 125 million people worldwide.[22] Unmet needs remain in the treatment of psoriasis. A population-based survey identified that approximately 30 percent of 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.[24] Psoriasis has a considerable psychological and quality of life impact, potentially affecting work, recreation, relationships, sexual functioning, family and social life.[25]

UCB Response to COVID-19
UCB is committed to helping those impacted by the novel coronavirus, COVID-19. This includes helping patients maintain access to and answering any questions about UCB medicines. We are also working closely with regulatory authorities to ensure the safety of all clinical trial participants and investigators, maintain compliance with good clinical practice, and minimize risks to trial integrity. The evolving COVID-19 pandemic has placed tremendous strain on medical healthcare systems worldwide as they focus on the ongoing extraordinary medical emergency. Taking this into consideration, UCB has taken measures to protect patients, healthcare providers, our employees, and the communities we serve around the world.

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 € 4.9 billion in 2019. 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.

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