UCB News

The Lancet Publishes Two Phase 3 Studies Detailing Bimekizumab Data in Moderate to Severe Plaque Psoriasis

- First two publications from the Phase 3 clinical development program of bimekizumab in psoriasis communicate comprehensive data from the BE VIVID and BE READY studies
- Bimekizumab, an investigational IL-17A and IL-17F inhibitor, is currently under review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of moderate to severe plaque psoriasis in adults

Brussels, Belgium – EMBARGOED FOR RELEASE: February 4, 2021, 23:30 PM GMT – UCB, a global biopharmaceutical company, today announced that *The Lancet* has published results from BE VIVID and BE READY, two Phase 3 studies evaluating the efficacy and safety profile of bimekizumab, its investigational IL-17A and IL-17F inhibitor, in the treatment of adults with moderate to severe plaque psoriasis.[1,2] The manuscripts of these two studies, published back to back, are the first publications from the Phase 3 clinical development program of bimekizumab in psoriasis. A comment piece accompanying these manuscripts is also published today.

"The simultaneous publication of data from two bimekizumab Phase 3 studies in one of medicine's most authoritative titles, *The Lancet*, speaks to the significance of these psoriasis studies. We're grateful to the patients and investigators who participated in the studies, and we're committed to working with the regulatory agencies to bring bimekizumab to patients," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of US, UCB.

Data from BE VIVID and BE READY showed that both studies met their co-primary endpoints, demonstrating that bimekizumab-treated patients achieved superior levels of skin clearance, at week 16, compared to those who received placebo or ustekinumab, as measured by at least a 90 percent improvement in the Psoriasis Area and Severity Index (PASI 90) and Investigator's Global Assessment (IGA) response of clear or almost clear skin (IGA 0/1); $p<0.0001$ for both comparisons.[1,2] These results were further supported by both studies meeting all ranked secondary endpoints including PASI 100 at week 16, PASI 75 at week 4, PASI 90 at week 52 (BE VIVID) and PASI 90 at week 56 in patients who achieved PASI 90 at week 16 (BE READY).[1,2] The safety profile of bimekizumab was consistent with earlier clinical studies with no new safety signals identified.[1,2,3,4]

Data from the BE VIVID and BE READY studies were included in the marketing application submissions to the FDA and EMA. In September 2020, UCB announced that the Company's Biologics License Application (BLA) and Marketing Authorization Application (MAA) for bimekizumab for the treatment of moderate to severe plaque psoriasis in adults had been accepted by the FDA and EMA, respectively.

The safety and efficacy of bimekizumab have not been established and it is not approved by any regulatory authority worldwide.

About the BE VIVID study[1]
BE VIVID was a Phase 3 multicentre, randomized, double-blinded, placebo- and active comparator-controlled trial comparing the efficacy and safety of bimekizumab with placebo and ustekinumab in adult patients with moderate to severe plaque psoriasis over 52 weeks. Patients (n=567) were randomized 4:2:1 to bimekizumab 320 mg every four weeks (Q4W), ustekinumab 45/90 mg (baseline weight-dependent dosing) at weeks 0/4, then every 12 weeks (Q12W), or placebo Q4W. At week 16, patients receiving placebo switched to bimekizumab 320 mg Q4W. The co-primary endpoints were proportions of patients achieving 90 percent improvement in the PASI 90 and 'clear' or 'almost clear' skin in the IGA (0/1) at week 16.

About the BE READY study[2]
BE READY was a Phase 3, multicentre, randomized, double-blinded, placebo-controlled trial. This study investigated the efficacy and safety of bimekizumab in adult patients with moderate to severe plaque psoriasis, the effects of treatment withdrawal, and two maintenance dosing schedules over 56 weeks. Patients (n=435) were randomized 4:1 to bimekizumab (320 mg every four weeks; Q4W) or placebo Q4W. Bimekizumab-

treated patients achieving PASI 90 at week 16 were re-randomized 1:1:1 to bimekizumab 320 mg Q4W, Q8W, or placebo for weeks 16–56. The co-primary endpoints were proportions of patients achieving 90 percent improvement in the PASI 90 and 'clear' or 'almost clear' skin in the IGA (0/1) at week 16.

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.[5] IL-17F has overlapping biology with IL-17A and drives inflammation independently of IL-17A.[6,7,8,9,10] Selective inhibition of IL-17F in addition to IL-17A suppresses inflammation to a greater extent than IL-17A inhibition alone.[9,10] The safety and efficacy of bimekizumab are being evaluated across multiple disease states as part of a robust clinical program.

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.[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 affects nearly three percent of the population, and approximately 125 million people worldwide have psoriasis.[13,14] 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.[15] Psoriasis has a considerable psychological and quality-of-life impact, potentially affecting work, recreation, relationships, sexual functioning, family and social life.[16]

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.

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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.

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