UCB News

The New England Journal of Medicine Publishes Results from Two Bimekizumab Phase 3 Studies in Moderate to Severe Plaque Psoriasis

- Today, two manuscripts published back to back detail the full results from the BE RADIANT and BE SURE studies, comparing the efficacy and safety of bimekizumab to secukinumab and adalimumab, respectively
- Results from BE RADIANT were also shared today as a late-breaking oral presentation at AAD VMX 2021
- In BE RADIANT, bimekizumab was superior to secukinumab in achieving complete skin clearance (PASI 100) at week 16, the primary endpoint of the study, and at week 48, a ranked secondary endpoint
- Bimekizumab 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 – April 23, 2021: 16:15 CEST – UCB, a global biopharmaceutical company, announced today that *The New England Journal of Medicine* has published two manuscripts with results from BE RADIANT and BE SURE, 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] Results from the Phase 3b BE RADIANT study were also shared today as a late-breaking oral presentation at the American Academy of Dermatology Virtual Meeting Experience 2021.[3] BE RADIANT is the first Phase 3 study to compare the efficacy and safety of dual IL-17A and IL-17F inhibition versus IL-17A inhibition alone.[1]

“The publication of data from BE RADIANT and BE SURE in *The New England Journal of Medicine* underscores the significance of these studies to the medical community, and closely follows the publication of the first two bimekizumab Phase 3 studies in *The Lancet* earlier this year”, said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. “Results published today reflect the high rates of complete skin clearance, PASI 100, at week 16, rapid response after one dose and durability of response up to one year seen with bimekizumab in previous studies.”

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

BE RADIANT RESULTS

The Phase 3b BE RADIANT study compared the efficacy and safety of bimekizumab to secukinumab in adults with moderate to severe plaque psoriasis.[1] The study met its primary endpoint, with significantly more patients treated with bimekizumab achieving complete skin clearance, as measured by a 100 percent improvement from baseline in the Psoriasis Area and Severity Index (PASI 100) at week 16, compared to those treated with secukinumab (61.7 percent versus 48.9 percent, respectively; $p<0.001$).[1]

The study also met all ranked secondary endpoints.[1] The superior levels of complete skin clearance observed at week 16 continued through to week 48, with 67.0 percent of patients treated with bimekizumab, achieving PASI 100, compared to 46.2 percent of patients treated with secukinumab ($p<0.001$).[1] At week 48, both bimekizumab maintenance dosing groups (every four weeks [Q4W] and every eight weeks [Q8W]), showed higher rates of complete skin clearance (PASI 100), compared with secukinumab ($p<0.001$).[1] In addition, at week 4, significantly more patients treated with bimekizumab achieved PASI 75 compared to patients treated with secukinumab (71.0 percent versus 47.3 percent, respectively; $p<0.001$).[1]

“In BE RADIANT, patients treated with bimekizumab achieved superior levels of complete skin clearance, PASI 100, compared with secukinumab-treated patients at week 16, the primary endpoint of the study, and up to 48 weeks of therapy. At week 4, a faster onset of response was also observed with bimekizumab compared with secukinumab. Data from this study support the value of inhibition of IL-17F in addition to IL-17A in the treatment of patients with moderate to severe plaque psoriasis.” said Prof. Kristian Reich, M.D., Ph.D., Translational Research in Inflammatory Skin Diseases, Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, Germany.

Across the study duration, the most common treatment-emergent adverse events (TEAEs) with bimekizumab were upper respiratory tract infections* (38.9 percent), oral candidiasis (19.3 percent) and urinary tract infection

(6.7 percent).[1] Oral candidiasis cases were predominantly mild or moderate and none led to discontinuation.[1] Over 48 weeks, the incidence of serious TEAEs was 5.9 percent with bimekizumab and 5.7 percent with secukinumab.[1]

BE SURE RESULTS
The Phase 3 BE SURE study compared the efficacy and safety of bimekizumab to adalimumab in adults with moderate to severe plaque psoriasis.[2] Results from the BE SURE study were previously reported at the European Academy of Dermatology and Venereology (EADV) Congress 2020.[4]

BE SURE met its co-primary endpoints, demonstrating that bimekizumab-treated patients achieved superior levels of skin clearance, at week 16, compared to those who received adalimumab, as measured by PASI 90 and Investigator's Global Assessment (IGA) response of clear or almost clear skin (IGA 0/1); $p<0.001$ for both comparisons.[2] These results were further supported by the study meeting all ranked secondary endpoints.[2] The safety profile of bimekizumab was consistent with earlier clinical studies with no new safety signals identified.[5,6,7,8]

In September 2020, UCB announced that the FDA and EMA had accepted the Company's Biologics License Application (BLA) and Marketing Authorization Application (MAA), respectively, for bimekizumab for the treatment of moderate to severe plaque psoriasis in adults. UCB is committed to bringing bimekizumab to patients worldwide and additional regulatory filings are underway.

**Upper respiratory tract infections include laryngitis, nasopharyngitis, pharyngeal abscess, pharyngitis, rhinitis, sinusitis, tonsilitis and upper respiratory tract infection.*

About Bimekizumab
Bimekizumab is an investigational humanized monoclonal IgG1 antibody that selectively and directly inhibits both IL-17A and IL-17F, two key cytokines driving inflammatory processes.[9] IL-17F has overlapping biology with IL-17A and drives inflammation independently of IL-17A.[10,11,12,13,14] Selective inhibition of IL-17F in addition to IL-17A suppresses inflammation to a greater extent than IL-17A inhibition alone.[13,14] 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.[15] 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.[16]

Approximately 125 million people worldwide are living with psoriasis, nearly three percent of the world's population.[17,18] 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.[19] Psoriasis has a considerable psychological and quality-of-life impact, potentially affecting work, recreation, relationships, sexual functioning, family and social life.[20]

About the BE RADIANT study[1]
BE RADIANT is a Phase 3b, randomized, multicenter, double-blind, active comparator-controlled, parallel-group study designed to assess the efficacy and safety of bimekizumab compared to secukinumab in adult subjects with moderate to severe chronic plaque psoriasis. BE RADIANT enrolled 743 participants with psoriasis for at least six months prior to the screening, a baseline PASI score ≥12, body surface area [BSA] affected by psoriasis ≥10% and IGA score ≥3.

Patients were randomized to bimekizumab (320 mg every Q4W) or secukinumab (300 mg weekly to week 4 and then Q4W).[3] From week 16, bimekizumab-randomized patients received treatment dosed Q4W or every 8 weeks (Q8W). The primary endpoint was PASI 100 response at week 16. Key secondary endpoints included PASI 100 at week 48 and PASI 75 at week 4.[1] Following the 48-week double-blinded period, patients were able to enroll in an ongoing 96-week open-label extension.

UCB announced top-line findings from BE RADIANT in July 2020.

About the BE SURE study[2]
BE SURE was a Phase 3, randomized, double-blind study comparing the efficacy and safety of bimekizumab to adalimumab in adult patients with moderate-to-severe chronic plaque psoriasis. The active-controlled initial treatment period of 24 weeks was followed by a dose-blind maintenance treatment period until week 56.

BE SURE enrolled 478 participants with chronic plaque psoriasis for at least six months prior to screening and with an affected body surface area of ≥10 percent, PASI of ≥12 and IGA score ≥three on a five-point scale. The co-primary endpoints of the study were PASI 90 response and IGA response at week 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 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’ 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

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