UCB News

Bimekizumab Superior to Cosentyx® in Achieving Complete Psoriasis Skin Clearance

- The Phase 3b BE RADIANT study met its primary endpoint and all ranked secondary endpoints
- Bimekizumab demonstrated superiority to Cosentyx® (secukinumab) for PASI 100 at week 16 and PASI 100 at week 48, with no new safety signals observed for bimekizumab
- These positive results confirm the speed, depth and durability of response seen with bimekizumab in three previous Phase 3 studies, and reinforce the importance of selectively inhibiting IL-17F, in addition to IL-17A

Brussels, Belgium – 24th July 2020, 7:00 AM CEST – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, today announced positive results from the Phase 3b BE RADIANT study, a direct comparison of the investigational IL-17A and IL-17F inhibitor, bimekizumab, to the IL-17A inhibitor, Cosentyx® (secukinumab) in the treatment of adult patients with moderate-to-severe plaque psoriasis.[1] BE RADIANT is the first head-to-head study comparing anti-IL-17 treatments, and the first study to demonstrate superiority to secukinumab for complete skin clearance at both weeks 16 and 48.

BE RADIANT met its primary endpoint at week 16 with statistical significance, demonstrating the superiority of bimekizumab over secukinumab for complete skin clearance, as measured by a 100 percent improvement in the Psoriasis Area and Severity Index (PASI 100).[1]

The BE RADIANT study also met all ranked secondary endpoints with statistical significance.[1] Bimekizumab was superior to secukinumab in achieving PASI 75 at week 4 and complete skin clearance at week 48, with both monthly (Q4 week) and bi-monthly (Q8 week) dosing.[1] The ongoing data assessment indicates that the safety profile of bimekizumab continues to be consistent with earlier clinical studies.[1,2,3,4,5]

“With BE RADIANT, bimekizumab has demonstrated superiority over secukinumab for complete skin clearance in adult patients with moderate-to-severe psoriasis. The results mark the latest positive data readout for bimekizumab, confirming the hypothesis that targeting IL-17F, in addition to IL-17A, suppresses inflammation to a greater extent than IL-17A inhibition alone in psoriasis,” said Professor Richard Warren, Salford Royal NHS Foundation Trust and The University of Manchester, United Kingdom.

“Psoriasis places a heavy burden on patients, often causing pain, discomfort and stigma. Patients may not get the complete skin clearance that they want and may not even realize that it’s possible. Healthcare providers may also feel forced to make trade-offs between therapies that work quickly, versus those that have shown durable efficacy. The BE RADIANT results demonstrate that bimekizumab has the potential to raise the treatment bar for patients and their dermatologists. UCB is proud to lead the way in connecting science to unmet patient needs and developing bimekizumab. It is our ambition to provide a transformative experience for psoriasis patients,” said Emmanuel Caeymaex, Executive Vice President Immunology Solutions and Head of US, UCB.

Bimekizumab has a robust Phase 3 psoriasis clinical development program. Detailed findings from the BE VIVID and BE READY studies were announced in June 2020 at the American Academy of Dermatology VMX, and the BE SURE results will be presented this year. The full BE RADIANT results will be presented to the scientific community in due course.

Bimekizumab’s safety and efficacy are also currently being evaluated in Phase 3 trials for potential indications in psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis and hidradenitis suppurativa.

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

About BE RADIANT
BE RADIANT is a randomized, multicenter double-blind, active comparator-controlled, parallel-group study designed to assess the efficacy and safety of bimekizumab compared with secukinumab in adult subjects with moderate-to-severe chronic plaque psoriasis.[6] BE RADIANT enrolled 743 participants with psoriasis for at least six months prior to the screening, a baseline PASI score ≥12 and body surface area [BSA] affected by psoriasis ≥10% and IGA score ≥3.[6]

The study consisted of a 48-week double-blind Treatment Period (final dose at week 44), and a further 96-week Open-Label Extension (OLE) Period. The primary endpoint was PASI 100 response (defined as a patient who achieves 100 percent improvement from baseline in the PASI score) at week 16. For additional details on the study, visit BE RADIANT on clinicaltrials.gov.[6]

Cosentyx® is a registered trademark of Novartis.

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.[7] IL-17F has overlapping biology with IL-17A and drives inflammation independently to IL-17A.[8,9,10,11,12] Selective inhibition of IL-17F in addition to IL-17A suppresses inflammation to a greater extent than IL-17A inhibition alone.[11,12] 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. 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.[13]

Psoriasis affects nearly three percent of the population, or about 125 million people worldwide.[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] Failure to achieve or retain complete and lasting skin clearance negatively impacts disease progression and quality of life.[16]

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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[1] UCB Data on File July 2020.
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