UCB News

First Presentations of Bimekizumab Phase 3 Data Demonstrate Superior Skin Clearance Over Placebo and Stelara® at Week 16 in Adults with Moderate-to-Severe Plaque Psoriasis

- Data from the Phase 3 BE VIVID and BE READY studies show that bimekizumab-treated patients with psoriasis achieved significant skin clearance at week 16, rapid response after one dose, and durability of response up to a year
- Results support the importance of selectively inhibiting IL-17F, in addition to IL-17A, with bimekizumab

Brussels, Belgium – 12 June 2020 – UCB, a global biopharmaceutical company, today announced the first presentations of data from the Phase 3 clinical development program of bimekizumab, its investigational IL-17A and IL-17F inhibitor, as part of a virtual session for the American Academy of Dermatology (AAD) 2020 Annual Meeting. Patients treated with bimekizumab achieved superior skin clearance in both the BE VIVID and BE READY Phase 3 studies, compared to those who received placebo or Stelara® (ustekinumab).[1,2] The majority of bimekizumab-treated patients in both studies achieved total skin clearance at week 16 and maintained their response for a year, as measured by the Psoriasis Area and Severity Index (PASI) 100 and Investigator Global Assessment (IGA) response of 0.[1,2]

Both studies evaluated the efficacy and safety of bimekizumab in adults with moderate-to-severe plaque psoriasis and met their co-primary superiority endpoints of at least a 90 percent improvement in the Psoriasis Area and Severity Index (PASI 90) and IGA response of clear or almost clear skin (IGA 0/1) at week 16, versus placebo.[1,2] The safety and efficacy of bimekizumab have not been established and it is not approved by any regulatory authority worldwide.

"We are delighted to share detailed results from the two bimekizumab Phase 3 studies, BE VIVID and BE READY. The majority of patients in these studies achieved rapid and lasting skin clearance. These positive results support the selective inhibition of IL-17F in addition to IL-17A, which suppresses inflammation to a greater extent than IL-17A inhibition alone. 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.

BE VIVID RESULTS

In BE VIVID, the pivotal Phase 3 study with active comparator ustekinumab, patients treated with bimekizumab 320 mg every four weeks (Q4W) achieved significantly superior skin clearance than those receiving placebo or ustekinumab at week 16, as measured by PASI 90 and IGA 0/1.[1] At the same time point, 58.6 percent of bimekizumab-treated patients achieved PASI 100 compared to 20.9 percent of ustekinumab-treated patients.[1] PASI 90 rates (all comparisons $p<0.001$) were – bimekizumab: 85.0 percent; ustekinumab: 49.7 percent; placebo: 4.8 percent; IGA 0/1 rates were – bimekizumab: 84.1 percent; ustekinumab: 53.4 percent; placebo: 4.8 percent.[1] Among patients who received one dose of bimekizumab, 76.9 percent achieved PASI 75 by week 4, versus 15.3 percent of ustekinumab-treated patients and 2.4 percent of patients who received placebo.[1]

BE VIVID results at week 52 show that bimekizumab sustained skin clearance, demonstrating superiority to ustekinumab.[1] PASI 100 was achieved by 64.2 percent of patients who received bimekizumab compared with 38 percent of those who received ustekinumab (nominal $p<0.001$).[1] A significantly greater proportion of bimekizumab-treated patients also achieved IGA 0/1 and PASI 90 at week 52 compared with ustekinumab-treated patients (77.9 percent versus 60.7 percent, and 81.6 percent versus 55.8 percent, respectively; $p<0.001$).[1] In the bimekizumab treatment arm, 38.9 percent of patients had received prior biologic therapy with an anti-TNF, anti-IL-17, or anti-IL-23 versus 38.7 percent in the ustekinumab treatment arm.[1]

The most frequently reported adverse events with bimekizumab through week 52 in BE VIVID were nasopharyngitis (21.8 percent), oral candidiasis (15.2 percent), and upper respiratory tract infections (9.1 percent).[1] The majority of adverse events were mild to moderate in intensity.[1] The vast majority of patients (94.7 percent) did not discontinue treatment.[1] The incidence of serious treatment-emergent adverse events (TEAEs) was 6.1 percent with bimekizumab versus 7.4 percent with ustekinumab at week 52.[1]

"The BE VIVID pivotal study results presented at AAD showcase bimekizumab's impressive speed and durability of response. The complete skin clearance results at week 16, as measured by PASI 100, further strengthen our belief in bimekizumab's potential to raise the bar for achieving long-lasting clear skin for people living with 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 and Skinflammation® Center, Hamburg, Germany, and BE VIVID Study Investigator.

BE READY RESULTS

In BE READY, the pivotal Phase 3 randomized withdrawal study, participants were randomized to bimekizumab 320mg Q4W or placebo for the first 16 weeks. Bimekizumab was superior to placebo in achieving PASI 90 and IGA 0/1 at week 16; over 90 percent of participants receiving bimekizumab achieved PASI 90 or IGA 0/1, while 68.2 percent achieved complete skin clearance (all $p<0.001$): PASI 90 (bimekizumab: 90.8 percent; placebo: 1.2 percent); IGA 0/1 (bimekizumab: 92.6 percent; placebo: 1.2 percent); PASI 100 (bimekizumab: 68.2 percent; placebo: 1.2 percent).[2]

In the second phase of the study, patients who had achieved at least a PASI 90 response at week 16 were re-randomized to receive continuous bimekizumab at two different dosing regimens (320 mg every four weeks or 320 mg every eight weeks) or to be withdrawn from treatment (placebo Q4W).[2] Evaluating the effects of continuous therapy with bimekizumab at two different dosing regimens (Q4W and Q8W) versus randomized withdrawal found that maintenance of response was similar in the two bimekizumab treatment arms, with 86.8 percent of patients who received continuous bimekizumab 320 mg Q4W maintaining PASI 90 at week 56, compared to 91 percent who were switched to bimekizumab 320 mg Q8W and 16.2 percent of patients who were withdrawn.[2]

In BE READY, the most frequently reported adverse events with bimekizumab between week 16 and week 56 were nasopharyngitis (10.4 percent for the Q4W group; 23 percent for the Q8W group), oral candidiasis (11.3 percent Q4W; 9.0 percent Q8W), and upper respiratory tract infections (11.3 percent Q4W; 8.0 percent Q8W).[2] The majority of adverse events were mild to moderate in intensity.[2] The vast majority of patients (100 percent Q4W; 98 percent Q8W) did not discontinue treatment.[2] The incidence of serious TEAEs with bimekizumab was 4.7 percent for the Q4W group and 3.0 percent for the Q8W group versus 3.8 percent with placebo at week 56.[2]

"As a serious chronic condition that requires long-term management, psoriasis can pose complex treatment challenges. Today's results demonstrate that bimekizumab may offer rapid and consistent skin clearance results over the course of 12 months, which represents a profound and meaningful evolution for many people living with psoriasis," said Dr. Kenneth Gordon, Professor and Thomas R Russell Family Chair of Dermatology, Medical College of Wisconsin, Milwaukee, WI.

Phase 2b data from the BE ABLE 2 psoriasis study will also be presented virtually for AAD 2020. These findings demonstrate bimekizumab's durability of response from week 12 to week 60, further supporting the results of the bimekizumab Phase 3 psoriasis clinical program.[3]

UCB has a robust clinical program for bimekizumab across multiple disease states. Top-line positive results from the comprehensive Phase 3 clinical program of bimekizumab in psoriasis were announced in Q4 2019. Full results from the placebo and adalimumab comparator BE SURE study will be presented at a future scientific congress. Phase 3 trials of bimekizumab in psoriatic arthritis, axial spondyloarthritis and hidradenitis suppurativa are also underway.

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The two late-breaking presentations cited in this release are:

Efficacy and safety of bimekizumab in patients with moderate-to-severe plaque psoriasis: results from BE VIVID, a 52-week Phase 3, randomized, double-blinded, ustekinumab- and placebo-controlled study,

Kristian Reich, Kim A. Papp, Andrew Blauvelt, Richard Langley, April Armstrong, Richard B. Warren, Kenneth Gordon, Joseph F. Merola, Cynthia Madden, Maggie Wang, Veerle Vanvoorden, Mark Lebwohl

Efficacy and safety of bimekizumab in patients with moderate-to-severe plaque psoriasis: results from BE READY, a 56-week Phase 3, randomized, double-blinded, placebo-controlled study with randomized withdrawal, Kenneth Gordon, Peter Foley, James Krueger, Andreas Pinter, Kristian Reich, Ronald Vender, Veerle Vanvoorden, Cynthia Madden, Luke Peterson, Andrew Blauvelt

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 patients with moderate-to-severe chronic plaque psoriasis.[4] 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.[4]

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 IGA 0 or 1 response (defined as clear or almost clear with at least a 2-category improvement relative to baseline) at week 16.[4] For additional details on the study, visit BE VIVID on clinicaltrials.gov.[4]

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.[5] 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.[5]

The co-primary endpoints of the study were PASI 90 response (defined as a patient who achieves at least 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.[5] For additional details on the study, visit BE READY on clinicaltrials.gov.[5]

Randomized withdrawal protocols are recommended by regulatory authorities as an enrichment strategy for clinical trials.[6] In this type of study, participants receive a test treatment for a specified time, and then are randomly assigned to continued treatment with the test drug or to placebo (i.e. withdrawal of active therapy).[6] Any difference between the two groups can demonstrate the effect of the active treatment.[6] The advantage of this design is that it is more ethical, as subjects receiving the experimental drug only do so if they respond to it, while subjects receiving placebo only do so until their symptoms return.[6]

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. UCB plans to submit applications to regulatory authorities for approval of bimekizumab to treat adults with moderate-to-severe plaque psoriasis in 2020.

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.

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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

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