UCB News

New Two-Year Data Showed Bimekizumab Maintained High Levels of Skin Clearance in Patients with Moderate to Severe Plaque Psoriasis

- Interim results from the BE BRIGHT open-label extension trial with bimekizumab, an investigational IL-17A and IL-17F inhibitor, were presented today at the 2021 AAD Summer Meeting
- Data showed that over nine out of 10 patients who achieved clear or almost clear skin (IGA 0/1) after 16 weeks of bimekizumab treatment maintained these responses through to two years with continuous maintenance dosing
- Over eight out of 10 patients who achieved complete skin clearance (PASI 100) at week 16 maintained PASI 100 responses through to two years of treatment with continuous maintenance dosing

Brussels, Belgium and Atlanta, Ga. – August 7th, 2021 – 20:00 CEST/14:00 EST – UCB, a global biopharmaceutical company, announced today new interim data from BE BRIGHT, an open-label extension (OLE) trial to assess the long-term safety, tolerability and efficacy of bimekizumab, an investigational IL-17A and IL-17F inhibitor, in adults with moderate to severe plaque psoriasis.[1,2] These results were presented today during a platform presentation at the 2021 American Academy of Dermatology (AAD) Summer Meeting, Tampa, Florida, U.S.

Data presented showed that the majority of patients who achieved complete or near complete skin clearance after 16 weeks of bimekizumab treatment maintained these responses through to two years with continuous maintenance dosing, every four weeks (Q4W) or every eight weeks (Q8W).[1] The efficacy and safety of bimekizumab have not been established and it is not approved by any regulatory authority worldwide.

“These interim results from the BE BRIGHT study highlight the potential of bimekizumab to provide lasting skin clearance to adults living with moderate to severe plaque psoriasis,” said Mark Lebwohl, MD, Dean for Clinical Therapeutics, Icahn School of Medicine at Mount Sinai, and Chairman emeritus, Kimberly and Eric J. Waldman Department of Dermatology and Presenting Author of the data at the AAD Summer Meeting. “These data are meaningful for the dermatology community and further add to the clinical evidence we have from the bimekizumab Phase 3 clinical program.”

“Given the chronic nature of psoriasis, physicians and patients value treatment options that can offer long-term disease control,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. “We are pleased to share the first presentation of bimekizumab data from the BE BRIGHT study highlighting the potential of bimekizumab to provide complete skin clearance that can last through to two years in adult patients with moderate to severe plaque psoriasis.”

Results shared today report on the maintenance of the Investigator’s Global Assessment (IGA) of Clear or Almost Clear skin (IGA 0/1), Body Surface Area (BSA) ≤1%, and Psoriasis Area and Severity Index (PASI) 100 through to two years of bimekizumab treatment.[1] Analyses included patients randomized to bimekizumab 320 mg Q4W who exhibited a response at week 16 in one of the pivotal Phase 3 studies (BE READY, BE VIVID, BE SURE), received bimekizumab 320 mg Q4W or Q8W maintenance dosing from week 16, and continued with the same maintenance dosing in the open-label BE BRIGHT study, i.e., Q4W/Q4W/Q4W or Q4W/Q8W/Q8W.[1]

Initially, 989 patients were randomized to bimekizumab Q4W. At week 16, 87.5 percent achieved IGA 0/1, 74.9 percent achieved BSA ≤1% and 62.7 percent achieved PASI 100. Among week 16 IGA 0/1 responders, over nine out of 10 patients maintained IGA 0/1 to week 48 in the OLE trial (94.4 and 96.2 percent with continuous Q4W and Q8W maintenance dosing, respectively).[1] Similarly, among week 16 BSA ≤1% responders, over nine out of 10 patients maintained BSA ≤1% to week 48 in the OLE trial (90.7 and 92.5 percent with continuous Q4W and Q8W maintenance dosing, respectively). Over eight out of 10 patients who achieved complete skin clearance (PASI 100) at week 16 maintained response to week 48 in the OLE trial (80.7 and 86.1 percent with continuous Q4W and Q8W maintenance dosing, respectively).[1]

In BE READY, BE VIVID and BE SURE, the most frequently reported treatment-emergent adverse events in bimekizumab-treated patients were nasopharyngitis, oral candidiasis, and upper respiratory tract infection.[3,4,5,6]

Bimekizumab is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe plaque psoriasis in adults. On June 25th, 2021, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending granting a marketing authorization for bimekizumab for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. The final decision of the European Commission on marketing authorization is expected within approximately two months of the CHMP opinion.

Notes to Editors:

About BE BRIGHT[2]
BE BRIGHT (NCT03598790) is an ongoing, multicentre, open-label extension study assessing the long-term safety, tolerability and efficacy of bimekizumab in adult patients with moderate to severe plaque psoriasis. Patients who completed one of three bimekizumab Phase 3 studies, BE READY, BE VIVID and BE SURE, were eligible to enroll in the BE BRIGHT study. More details can be found at ClinicalTrials.gov.

About bimekizumab
Bimekizumab is an investigational humanized IgG1 monoclonal antibody that is designed to selectively and directly inhibit both IL-17A and IL-17F, two key cytokines driving inflammatory processes.[4,5,6] Selective inhibition of IL-17F in addition to IL-17A has been shown to suppress inflammation to a greater extent than IL-17A inhibition alone.[4,5,6]

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

About Psoriasis
Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin.[7] This skin condition affects men and women of all ages and ethnicities.[7] 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.[8] Psoriasis also has a considerable psychological and quality-of-life impact, potentially affecting work, recreation, relationships, sexual functioning, family and social life.[9]

Unmet needs remain in the treatment of psoriasis. A population-based survey identified that approximately one in three 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.[10]

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.

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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

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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.

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