UCB News

Bimekizumab Phase 3 Psoriasis Study Demonstrates Superiority Versus Humira®

- The BE SURE study, comparing bimekizumab to Humira® (adalimumab) for the treatment of adults with moderate-to-severe plaque psoriasis, met all co-primary and ranked secondary endpoints
- BE SURE is the third Phase 3 bimekizumab psoriasis study to report positive results since October
- UCB will submit applications to regulatory authorities for approval of bimekizumab to treat adults with moderate-to-severe plaque psoriasis in mid-2020

Brussels, Belgium – 06 December 2019, 7:00 AM CET – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, today announced positive results from the Phase 3 active-controlled BE SURE study. BE SURE compared the investigational IL-17A and IL-17F inhibitor bimekizumab to the TNF inhibitor adalimumab in the treatment of adults with moderate-to-severe plaque psoriasis. BE SURE met its co-primary endpoints at week 16, demonstrating superiority of bimekizumab to adalimumab in achieving at least a 90 percent improvement in the Psoriasis Area and Severity Index (PASI 90) and Investigator Global Assessment (IGA) response of clear or almost clear (IGA 0/1).[1]

The BE SURE study also met all of its ranked secondary endpoints with statistical significance, including superior total skin clearance at weeks 16 and 24, as measured by PASI 100, compared to adalimumab.[1] Furthermore, bimekizumab was statistically superior to adalimumab in achieving rapid response, defined as PASI 75 at week 4.[1] During the dose-blind maintenance period, high levels of skin clearance were maintained with bimekizumab through week 56.[1] The continued data assessment indicates that the safety profile of bimekizumab was consistent with earlier clinical studies.[2,3,4] The full BE SURE results will be presented at a scientific congress in 2020.

BE SURE is the third Phase 3 bimekizumab study to report positive results since October. It follows findings from BE VIVID[3] and BE READY[2] – studies evaluating the efficacy and safety of bimekizumab in adults with moderate-to-severe plaque psoriasis. The safety and efficacy of bimekizumab have not been established and it is not approved by any regulatory authority worldwide.

“Active-controlled trials are a key way to inform our clinical understanding and decision making in psoriasis. The results of BE SURE confirmed the superiority of bimekizumab to a widely used TNF inhibitor in psoriasis and further demonstrated the important role of selectively targeting IL-17A and IL-17F,” said Prof. Kristian Reich, M.D., Ph.D., Center for 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 SURE Lead Study Investigator.

“Today’s BE SURE findings are consistent with the positive results we recently announced for both BE VIVID and BE READY. UCB is committed to addressing the critical unmet needs of adult patients with moderate-to-severe plaque psoriasis, particularly complete skin clearance. Our Phase 3 studies have shown that bimekizumab has the potential to make a meaningful difference for these patients,” said Iris Loew-Friedrich, Head of Drug Development and Chief Medical Officer, UCB.

The safety and efficacy of bimekizumab are also being evaluated in psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis, with first top-line results expected by the end of 2021.

About BE SURE
BE SURE is a Phase 3, randomized, double-blind study comparing bimekizumab to adalimumab in adult patients with moderate-to-severe chronic plaque psoriasis. The active-controlled initial treatment period of 24 weeks is 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 at least 10 percent, PASI of at least 12 and IGA score equal to or greater than three on a five-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. For additional details on the study, visit BE SURE on clinicaltrials.gov.[5]

Humira® is a registered trademark of AbbVie, Inc.

About Bimekizumab
Bimekizumab is an investigational humanized monoclonal IgG1 antibody that potently and selectively neutralizes IL-17A and IL-17F, two key cytokines driving inflammatory processes.[6] IL-17A and IL-17F have similar pro-inflammatory functions and independently synergize with other inflammatory mediators to drive chronic inflammation and damage across multiple tissues.[7,8]

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.[9]

Psoriasis affects nearly three percent of the population, or about 125 million people worldwide.[9] 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.[10] Failure to achieve or retain complete and lasting skin clearance negatively impacts disease progression and quality of life.[11,12]

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 7 500 people in approximately 40 countries, the company generated revenue of € 4.6 billion in 2018. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

Forward looking statements
This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not a guarantee of future performance and

are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, 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, product liability claims, challenges to patent protection for products or product candidates, 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.

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There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed.

Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.

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