UCB News

Bimekizumab Positive Results Confirmed in Second Phase 3 Psoriasis Study

- The Phase 3 BE READY study, evaluating the efficacy and safety of bimekizumab versus placebo in adults with moderate-to-severe chronic plaque psoriasis, met all primary and ranked secondary endpoints[1]
- UCB plans to submit applications to regulatory authorities for approval of bimekizumab to treat adults with moderate-to-severe plaque psoriasis in mid-2020

Brussels, Belgium – 15th November 2019, 7:00 AM CET – Regulated Information – Inside Information – UCB, a global biopharmaceutical company, today announced positive results from BE READY, the second of three Phase 3 studies this year to report findings on the investigational treatment bimekizumab.[1] BE READY evaluated the efficacy and safety of the IL-17A and IL-17F inhibitor bimekizumab in the treatment of adults with moderate-to-severe plaque psoriasis. This randomized withdrawal study met its co-primary endpoints of 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) at week 16, compared to placebo.[1]

Among key secondary endpoints, bimekizumab was statistically superior to placebo in achieving total skin clearance (PASI 100) at week 16.[1] In addition, bimekizumab was statistically superior to placebo in patient-reported reductions in itch, pain and scaling, as well as clear or almost clear scalp (scalp IGA), at week 16.[1] Bimekizumab was also statistically superior to placebo in achieving rapid response, defined as PASI 75 at week 4. Furthermore, after an initial week-16 response, continued treatment with bimekizumab resulted in a statistically superior response at week 56 compared to placebo, during the randomized withdrawal period of the study.[1] The initial data assessment indicates that the safety profile of bimekizumab was consistent with earlier clinical studies.[2,3] The full BE READY results will be presented at a scientific congress in 2020.

These data follow the positive clinical results recently reported from the Phase 3 BE VIVID study, evaluating the efficacy and safety of bimekizumab versus placebo and ustekinumab, in adults with moderate-to-severe plaque psoriasis. The study met all primary and ranked secondary endpoints, with bimekizumab showing statistically significant superiority to placebo and ustekinumab in achieving skin clearance and disease improvement at week 16.[2] The safety and efficacy of bimekizumab have not been established and it is not approved by any regulatory authority worldwide.

“The bimekizumab Phase 3 development program continues to deliver impressive results, with BE READY being the second study to show strong and consistent outcomes with this drug. Psoriasis places a heavy burden on patients, often causing pain, discomfort and stigma. Clinical trial results with bimekizumab continue to show both robust skin clearance rates as well as improvements in itch, pain and scaling – critically important elements for people living with this disease,” said Andrew Blauvelt, M.D., M.B.A., Lead Study Investigator and President, Oregon Medical Research Center in Portland, Oregon.

“We are delighted to announce positive data on bimekizumab for the second time in just four weeks. UCB is now preparing for a bimekizumab submission to regulatory authorities in mid-2020 to bring this promising treatment option to people living with psoriasis. With the ongoing success of our clinical program for bimekizumab, UCB continues to deliver on its Patient Value Strategy to connect the unmet needs of patients with innovative science,” 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 (PsA), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).

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. 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.

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 READY on clinicaltrials.gov.[4]

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.[5] 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.[6,7]

About Psoriasis
Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin. The 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 thicken, pitted or ridged nails.[8]

Psoriasis affects nearly three percent of the population, or about 125 million people worldwide.[8] 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.[9] Failure to achieve or retain complete and lasting skin clearance negatively impacts disease progression and quality of life.[10,11]

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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 guarantees 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.

[1] UCB Data on File November 2019.
[2] UCB Data on File October 2019.
[3] Papp K, Merola J, Gottlieb A, et al. Dual neutralization of both interleukin 17A and interleukin 17F with bimekizumab in patients with psoriasis: Results from BE ABLE 1, a 12-week randomized, double-blinded, placebo-controlled phase 2b trial. J Am Acad Dermatol. 2018 Aug;79(2):277-286.e10. doi: 10.1016/j.jaad.2018.03.037. Epub 2018 Mar 30.
[4] ClinicalTrials.gov. A Study With a Initial Treatment Period Followed by a Randomized-withdrawal Period to Evaluate the Efficacy and Safety of Bimekizumab in Adult Subjects With Moderate to Severe Chronic Plaque Psoriasis (BE READY). Available at: https://clinicaltrials.gov/ct2/show/NCT03410992. Last accessed: November 2019.

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