UCB News

Bimekizumab Phase 3 Psoriasis Study Meets All Endpoints, Achieving Significantly Greater Efficacy Versus Placebo and Ustekinumab

- The Phase 3 BE VIVID study evaluating the efficacy and safety of bimekizumab in adults with moderate-to-severe chronic plaque psoriasis met all primary and ranked secondary endpoints[i]
- Bimekizumab showed statistically significant superiority to placebo and ustekinumab in achieving skin clearance and disease improvement at Week 16[i]
- The BE VIVID results are the first from the ongoing bimekizumab Phase 3 development program

Brussels, Belgium – 17 October 2019, 7.00 AM CET – Regulated Information - Inside Information - UCB, a global biopharmaceutical company, today announced positive results from BE VIVID, the first of three Phase 3 studies evaluating the efficacy and safety of bimekizumab, an IL-17A and IL-17F inhibitor, in the treatment of adults with moderate-to-severe chronic plaque psoriasis. Results showed that after 16 weeks of treatment, bimekizumab met the co-primary endpoints of at least a 90 percent improvement in the Psoriasis Area and Severity Index (PASI 90) and Investigator Global Assessment (IGA) score of clear or almost clear (IGA 0/1).[i]

Among key secondary endpoints, bimekizumab was also found to be superior to ustekinumab in reaching PASI 90 and IGA 0/1 and superior to placebo in total skin clearance (PASI 100 or IGA 0) at Week 16.[i] The initial assessment indicates that the safety profile of bimekizumab was consistent with the earlier BE ABLE Phase 2 studies.[ii]

The safety and efficacy of bimekizumab has not been established and it is not approved by any regulatory authority worldwide. The full BE VIVID results will be presented in due course.

“These encouraging first results provide strong evidence that bimekizumab has the potential to raise the bar for achieving skin clearance rates for patients. Achieving clear skin is of critical importance in positively impacting the lives of psoriasis patients. Today’s announcement marks an important milestone in the extensive clinical development of bimekizumab,” said Mark Lebwohl, M.D., Lead Study Investigator, Waldman Professor of Dermatology and Chair of the Kimberly and Eric J. Waldman Department of Dermatology at the Icahn School of Medicine at Mount Sinai, New York.

“Psoriasis affects all aspects of a patient’s life. We believe that bimekizumab has the potential to be a meaningful new treatment option for people living with psoriasis,” said Iris Loew-Friedrich, Head of Drug Development and Chief Medical Officer, UCB. “Today’s positive BE VIVID results are just the start. We look forward to sharing further findings from the bimekizumab clinical development program in the coming months.”

The safety and efficacy of bimekizumab is also being evaluated in psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).

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. 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.

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

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.[iii] 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.[iv,v]

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 thickened, pitted or ridged nails.[vi]

Psoriasis affects nearly 3 percent of the population, or about 125 million people worldwide.[vi] 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.[vi] Failure to achieve or retain complete and lasting skin clearance negatively impacts disease progression and quality of life.[viii,ix]

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

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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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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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[i] UCB Data on File October 2019

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