Bimekizumab Demonstrates Skin Clearance in Phase 2b Psoriasis Study with first monoclonal antibody neutralizing both IL-17A and IL-17F

Positive top line results from the UCB BE ABLE study

- The Phase 2b BE ABLE study met the primary objective of establishing dose response, with up to 79% of patients achieving at least 90% skin clearance in the psoriasis area and severity index (PASI90) at week 12
- Up to 60% of patients achieved complete skin clearance at week 12 as measured by PASI100, a secondary efficacy variable
- Bimekizumab is a monoclonal antibody rationally designed to potently and selectively neutralize both IL-17A and IL-17F, two key pro-inflammatory cytokines involved in the pathophysiology of psoriasis
- The BE ABLE study provides the first Phase 2b results with this novel therapeutic approach, indicating that bimekizumab may offer psoriasis patients a promising new therapeutic option
- UCB is ready to advance the Phase 3 clinical development program for bimekizumab in psoriasis and continues to advance earlier stage clinical trials in psoriatic arthritis and ankylosing spondylitis

Brussels, Belgium – 21 July, 7:00 AM CET – Regulated Information – Inside Information – UCB today announced positive results from BE ABLE, a Phase 2b study to investigate the safety, efficacy, pharmacokinetics (PK), and pharmacodynamics (PD) of bimekizumab compared with placebo in adult patients with moderate to severe chronic plaque psoriasis. The study met the primary objective of establishing dose response for bimekizumab, and demonstrated significant efficacy compared to placebo.[1]

“Because bimekizumab targets inflammation associated with psoriasis on two fronts, neutralizing IL-17A and IL-17F cytokines, it has the potential to raise the bar for achieving and maintaining skin clearance rates. A complete and specific blockade of inflammation is key to achieving strong results,” said Kim Papp, MD, PhD, lead investigator of the BE ABLE study and President of Probity Medical Research. “The results with bimekizumab are striking, especially because a stringent PASI 90 primary efficacy threshold was used. Our results showed that a remarkably high number of patients treated with bimekizumab rapidly achieved clear skin. Rapidly achieving clear or almost clear skin is of critical importance for positively impacting patient lives."

“Psoriasis takes a deep and lasting emotional and physical toll on patients and has historically been difficult to treat. It is now widely recognized that psoriasis is more than a skin disease, with significant involvement of other body systems. There is still a need to control both skin symptoms and systemic inflammation more effectively, which is why new therapies are required. These results show that bimekizumab has the potential to be a valuable treatment option for psoriasis patients,” said Andrew Blauvelt, MD, MBA, an investigator in the trial and President of Oregon Medical Research Center in Portland, Oregon.

Inspired by patients.
Driven by science.

“UCB is executing on its Patient Value Strategy to connect the unmet needs of patients with innovative science. In developing bimekizumab, we tested the novel hypothesis that neutralizing both IL-17A and IL-17F can deliver superior outcomes for psoriasis and psoriatic arthritis patients. The results of the BE ABLE study show that bimekizumab may provide fast and significant skin clearance for patients living with moderate-to-severe plaque psoriasis. UCB is ready to rapidly advance our Phase 3 psoriasis clinical development program. We are also developing bimekizumab in further underserved disease states, including psoriatic arthritis, where we have already seen promising results in early clinical research, and in ankylosing spondylitis,” said Emmanuel Caeymaex, Head of Immunology and Executive Vice President at UCB.

The primary efficacy variable evaluated in the Phase 2b BE ABLE study was the percentage of patients who achieved at least 90% disease improvement from baseline as measured by the Psoriasis Area and Severity Index (PASI 90) at week 12. Bimekizumab achieved this clinical response threshold for a significantly greater number of patients than placebo across multiple doses.[1]

Additionally, bimekizumab showed a favourable safety profile with no new safety signals observed. The most common adverse events observed were runny nose (nasopharyngitis) and common cold (upper-respiratory tract infection). [1]

UCB plans to present and publish the full results of BE ABLE in early 2018.

About Bimekizumab
Bimekizumab is the first humanized monoclonal IgG1 antibody that potently and selectively neutralizes both IL-17A and IL-17F, two key cytokines driving inflammatory processes. IL-17A and IL-17F are the most closely related members of the IL-17 family of cytokines. They are both co-expressed at sites of inflammation and have overlapping pro-inflammatory functions. Both IL-17A and IL-17F can independently cooperate with other inflammatory mediators to drive chronic inflammation and tissue destruction.

Previous early phase clinical studies in psoriasis and psoriatic arthritis have suggested that dual neutralization of both IL-17A and IL-17F with bimekizumab may provide a new targeting approach for the treatment of immune-mediated inflammatory diseases.[4,5] Preclinical results in disease-relevant cells have shown that dual neutralization of both IL-17A and IL-17F reduces the expression of inflammation-related genes and production of inflammatory cytokines to an extent greater than inhibition of IL-17A or IL-17F alone.[6,7]

Within UCB’s core antibody discovery platform, bimekizumab was designed following a proprietary, rational, structure-based approach to build dual specificity and strong affinity for both IL-17A and IL-17F in a humanized IgG1 monoclonal antibody. By potently and selectively targeting both IL-17A and IL-17F, bimekizumab may have the potential to achieve a more complete and specific inhibition of chronic inflammation across multiple tissues. Because of its targeted anti-inflammatory potential, UCB is also studying bimekizumab in other disease areas, including psoriatic arthritis and ankylosing spondylitis. Bimekizumab is not approved by any regulatory authority worldwide.

About Psoriasis

Psoriasis is a common, chronic, immune-mediated inflammatory disease with symptoms that mostly affect the skin. Patients with psoriasis may have some or all of the following symptoms: red patches of skin covered with silvery scales, cracked skin that may bleed and thicken, severe itching and pitted or ridged nails.[8] Because of its visible and physically debilitating aspects, psoriasis often takes an emotional toll on patients, causing increased self-consciousness, frustration, fatigue, depression, and even suicidal ideation. People living with psoriasis frequently report sleeping problems, difficulties at work, problems interacting with family members, disrupted leisure activities, and sexual difficulties. Patients also report that the significant impact of this disease on their quality of life is not well understood by their physicians.[10]

Psoriasis affects nearly three percent of the world's population, or approximately 125 million people worldwide. Women and men of all ages and ethnicities are affected by psoriasis. Psoriasis has a variety of forms, though plaque psoriasis is most common, comprising approximately 80% to 90% of all cases.[2] Several other serious diseases have been associated with psoriasis, including diabetes, heart disease, and psoriatic arthritis, a chronic disease that causes inflammation, swelling, and pain in the joints.[9]

As research continues to demonstrate the serious, systemic effects of psoriasis, new research approaches to understand effective treatment options are needed to improve the health and lives of psoriasis patients.

About BE ABLE

BE ABLE is a multi-center, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study of bimekizumab compared with placebo in adult patients with moderate to severe chronic plaque psoriasis. The study included a 12-week treatment period, after which eligible patients could enroll in an extension study. For those not enrolling in the extension study, a safety follow-up visit was conducted 20 weeks after the last dose of study medication.[2]

The study included 250 patients with chronic plaque psoriasis with an affected body surface area of at least 10% and PASI of at least 12. Patients were randomized into six dosing regimens to receive either placebo or bimekizumab every four weeks subcutaneously. Randomization was balanced across treatment groups.[2]

PASI is a score used by health care professionals to express the severity of psoriasis as measured by body surface area affected by the disease and severity of lesions. It is widely used to assess the skin improvement of people receiving treatment for psoriasis, particularly in clinical trials.[3] In BE ABLE, efficacy was measured by the proportion of people who achieved a 90% improvement (PASI90, the primary efficacy variable) at week 12.[2] By comparison, most previous trials in psoriasis have used the proportion of people who achieve a 75% improvement in the skin affected (PASI75), as the primary threshold for evaluating psoriatic skin clearance.

The secondary efficacy variables assessed in BE ABLE were Investigator's Global Assessment of response (IGA) defined as clear or almost clear skin with at least 2 category improvement from baseline at week 8 and at week 12, PASI90 response at week 8, PASI75 response at week 12, and PASI100 response at week 12.[2]

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