UCB News

UCB Announces Positive Phase 3 Studies for Bimekizumab in Hidradenitis Suppurativa

- Top-line results show that the two Phase 3 studies, BE HEARD I and BE HEARD II, met their primary and key secondary endpoints with statistical significance and consistent clinical relevance
- First Phase 3 evidence to suggest that targeting IL-17F in addition to IL-17A may be a promising treatment approach in adults with moderate to severe hidradenitis suppurativa
- Results from these two studies will form the basis of global regulatory applications for bimekizumab in hidradenitis suppurativa starting in Q3 2023

Brussels (Belgium), 9th December 2022 – 07:00 (CET) – **Regulated information – Inside information –** UCB, a global biopharmaceutical company, today announced positive top-line results from two Phase 3 studies, BE HEARD I and BE HEARD II, evaluating the efficacy and safety of bimekizumab in adults with moderate to severe hidradenitis suppurativa.[1,2] The positive results from these two studies will form the basis of global regulatory license applications for bimekizumab in hidradenitis suppurativa starting in Q3 2023. The safety and efficacy of bimekizumab in hidradenitis suppurativa have not been established, and it is not approved for use in hidradenitis suppurativa by any regulatory authority worldwide.

"We are excited to announce positive pivotal Phase 3 outcomes in moderate to severe hidradenitis suppurativa which support our strong belief in bimekizumab and provide the first Phase 3 evidence suggesting that targeting IL-17F in addition to IL-17A may be a promising treatment approach. We look forward to bringing bimekizumab to people living with this chronic inflammatory disease as soon as possible," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

Across the two studies, bimekizumab met the primary endpoint, demonstrating statistically significant and consistent clinically meaningful improvements over placebo in the proportion of patients who achieved the Hidradenitis Suppurativa Clinical Response (HiSCR50) at week 16.[1,2] Bimekizumab demonstrated depth of response with statistically significant improvements at week 16 over placebo in the percentage of patients achieving HiSCR75, a key secondary endpoint in both studies.[1,2] HiSCR50 and HiSCR75 are defined as at least either a 50 or 75 percent reduction from baseline in the total abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count.[3,4] The safety profile of bimekizumab in both studies was consistent with previously reported studies with no new observed safety signals.[1,2]

"Hidradenitis suppurativa is a chronic, painful and debilitating inflammatory skin disease that impacts patients' physical, psychological, and social well-being. This reduced quality of life is compounded by the limited treatment options currently available," said Professor Gregor Jemec, MD, Ph.D., Chairman, Department of Dermatology Zeeland University, Roskilde, Denmark. "The positive top-line clinical outcomes from BE HEARD I and BE HEARD II are promising and demonstrate the value that bimekizumab can potentially bring to the hidradenitis suppurativa community."

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Detailed results from BE HEARD I and BE HEARD II will be presented at an upcoming scientific meeting and published in a peer-reviewed medical journal.

Notes to editors:

About BE HEARD I

BE HEARD I is a randomized, double-blind, placebo-controlled, parallel group, multicenter, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in adults with moderate to severe hidradenitis suppurativa.[3] BE HEARD I enrolled 505 participants with a diagnosis of moderate to severe hidradenitis suppurativa.[3] For additional details on the study, visit BE HEARD I on clinicaltrials.gov.[3]

About BE HEARD II

BE HEARD II is a randomized, double-blind, placebo-controlled, parallel group, multicenter, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in adults with moderate to severe hidradenitis suppurativa.[4] BE HEARD II enrolled 509 participants with a diagnosis of moderate to severe hidradenitis suppurativa.[4] For additional details on the study, visit BE HEARD II on clinicaltrials.gov.[4]

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) is a chronic, recurring, painful, and debilitating inflammatory skin disease.[5,6] The main symptoms are nodules, abscesses, and pus-discharging fistulas (channels leading out of the skin) which typically occur in the armpits, groin and buttocks.[5,6] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[5,6]

HS develops in early adulthood, affects approximately one percent of the population in most studied countries and is three times more common in women than in men.[5,6] Approximately one third of people with HS have a family history of HS, and lifestyle factors such as smoking and obesity can also play a crucial role in the clinical course of HS.[7]

The symptoms of pain, discharge and scarring are not only a physical burden. People with HS also experience stigma: worrying about or directly experiencing negative attitudes and reactions from society in response to their symptoms.[8] These feelings can lead to embarrassment, social isolation, low self-esteem and sexual life impairment, and impact all areas of life, including interpersonal relationships, education and work.[5,7]

About bimekizumab

Bimekizumab is a humanized monoclonal IgG1 antibody that is designed to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), two key cytokines driving inflammatory processes.[9]

In August 2021, bimekizumab was approved in the European Union (EU)/European Economic Area (EEA) and in Great Britain, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for

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systemic therapy.[10,11] The label information may differ in other countries. Please check local prescribing information.

BIMZELX® ▼ (bimekizumab) EU/EEA Important Safety Information in Psoriasis

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5 percent) (most frequently nasopharyngitis) and oral candidiasis (7.3 percent). Common adverse reactions (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, headache, dermatitis and eczema, acne, injection site reactions, fatigue. Elderly may be more likely to experience certain adverse reactions such as oral candidiasis, dermatitis and eczema when using bimekizumab.

Bimekizumab is contraindicated in patients with hypersensitivity to the active substance or any of the excipients and in patients with clinically important active infections (e.g. active tuberculosis).

Bimekizumab may increase the risk of infections. Treatment with bimekizumab must not be administered in patients with any clinically important active infection. Patients treated with bimekizumab should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. Prior to initiating treatment with bimekizumab, patients should be evaluated for tuberculosis (TB) infection. Bimekizumab should not be given in patients with active TB and patients receiving bimekizumab should be monitored for signs and symptoms of active TB.

Cases of new or exacerbations of inflammatory bowel disease have been reported with bimekizumab. Bimekizumab is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, bimekizumab should be discontinued and appropriate medical management should be initiated.

Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, administration of bimekizumab should be discontinued immediately and appropriate therapy initiated.

Live vaccines should not be given in patients treated with bimekizumab.

Please consult the summary of product characteristics in relation to other side effects, full safety and prescribing information. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

EU summary of product characteristics date of revision December 2022

Last accessed: December 2022.

▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions*

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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 approximately 8,600 people in approximately 40 countries, the company generated revenue of €5.8 billion in 2021. 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 COVID-19, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, 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, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, 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. There is no guarantee that new product candidates will be discovered or identified in the pipeline, will progress to product approval or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products, which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB's efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting

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biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

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.

UCB is providing this information, including forward-looking statements, only as of the date of this press release and it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated otherwise. UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. UCB expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.

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