UCB News

UCB to Present Eight Bimekizumab Abstracts at AAD 2023 with Results from Studies in Psoriasis, Psoriatic Arthritis and Hidradenitis Suppurativa

- Phase 3 data on investigational bimekizumab in the treatment of adults with moderate to severe hidradenitis suppurativa to be presented as a late-breaking platform presentation

Brussels (Belgium), 16th March 2023 – 07:00 (CET) – UCB, a global biopharmaceutical company, today announced that it will present eight bimekizumab abstracts across a range of IL-17 mediated diseases[1,2] – *moderate to severe plaque psoriasis, active psoriatic arthritis (PsA) and moderate to severe hidradenitis suppurativa (HS)* – at the 2023 American Academy of Dermatology (AAD) Annual Meeting in New Orleans, U.S., 17–21 March. The abstracts have been accepted as one late-breaking oral platform presentation and seven posters including three with oral presentations. The platform presentation will share the first detailed data from the two Phase 3 studies, BE HEARD I and BE HEARD II, evaluating the efficacy and safety of bimekizumab compared with placebo in the treatment of adults with moderate to severe HS.[3,4]

"The Phase 3 results for hidradenitis suppurativa further demonstrate UCB's dedication to improving treatment options for patients with chronic diseases and reinforce our commitment to advancing dermatological care through cutting-edge science," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

In the U.S., the efficacy and safety of bimekizumab have not been established for any indication and it is not approved by the U.S. Food and Drug Administration. In the European Union and Great Britain, bimekizumab is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[5,6] UCB is investigating bimekizumab in PsA and HS. The efficacy and safety of bimekizumab in PsA and HS have not been established, and it is not approved for use in these indications by any regulatory authority worldwide.

Five of the eight abstracts at AAD 2023 will share data on bimekizumab in the treatment of moderate to severe plaque psoriasis including data evaluating bimekizumab in the treatment of nail psoriasis from the BE RADIANT phase 3b trial. Two abstracts evaluating bimekizumab for the treatment of active PsA will also be presented.

The following is a guide to the UCB-sponsored abstracts at AAD 2023:

Hidradenitis Suppurativa

- Bimekizumab in patients with moderate-to-severe hidradenitis suppurativa: 48-week efficacy and safety from BE HEARD I & II, two phase 3, randomized, double-blind, placebo controlled, multicenter studies.
  Kimball AB, Zouboulis CC, Sayed C et al.
  Saturday March 18: 13:00–13:10

Psoriasis

- Bimekizumab maintenance of response and safety in patients with moderate to severe plaque psoriasis: Results from the open-label extension period (Weeks 48–144) of the BE RADIANT phase 3b trial
  Strober B, Puig L, Blauvelt A et al.
  # 43778
  Sunday March 19: 13:00–13:05

- Bimekizumab versus secukinumab for the treatment of nail psoriasis in patients with moderate to severe plaque psoriasis: Results from the BE RADIANT phase 3b trial
  Eyerich K, Gottlieb AB, Piaserico S et al.
  # 43878
  Sunday March 19: 13:30–13-35

- Bimekizumab safety and tolerability in patients with moderate to severe plaque psoriasis: Analysis of pooled data from up to three years of treatment in five phase 3/3b clinical trials
  Gordon KB, Gooderham M, Foley P et al.
  # 43758
  Sunday March 19: 15:10–15:15

- Itching in patients with moderate to severe plaque psoriasis: The relationship between improvements in Psoriasis Area and Severity Index and patient-reported symptoms in the BE RADIANT phase 3b trial
  Augustin M, Langley RG, Warren RB et al.
  # 42664

- Bimekizumab in patients with moderate to severe plaque psoriasis: Injection site reactions through two years of the BE RADIANT phase 3b trial and open-label extension with one-year comparison to secukinumab
  Soung J, Rosmarin D, López Ferrer A et al.
  # 43802

Psoriatic Arthritis

- Bimekizumab improved efficacy measures in patients with active psoriatic arthritis and moderate or severe psoriasis: Pooled 16-week results from phase 3 randomized, placebo-controlled studies BE OPTIMAL and BE COMPLETE
  Gottlieb AB, Asahina A, Merola JF et al.
  # 43024

- Bimekizumab in bDMARD-naïve patients with psoriatic arthritis and skin involvement: Analysis of radiographic progression at Week 16 of BE OPTIMAL, a phase 3, multicenter, randomized, placebo-controlled, active reference study
  Merola JF, Asahina A, Gisondi P et al.
  # 43744

Notes to editors:

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.[5,7] In the U.S., the efficacy and safety of bimekizumab have not been established for any indication and it is not approved by the U.S. Food and Drug Administration.

In August 2021, bimekizumab was first 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 systemic therapy.[5,6] The label information may differ in other countries where approved. Please check local prescribing information.

About BIMZELX® ▼ (bimekizumab) in the EU/EEA
In the EU/EEA, BIMZELX® is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[5]

BIMZELX® ▼ (bimekizumab) EU/EEA Important Safety Information in Psoriasis
The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%) (most frequently nasopharyngitis) and oral candidiasis (7.3%). 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: March 2023.

▼ *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 €5.5 billion in 2022. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

Forward looking statements
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 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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