

UCB to Present New Bimekizumab Data in Hidradenitis Suppurativa, Psoriasis and Psoriatic Arthritis at EADV 2023

Brussels (Belgium), 9 October 2023 (07:00 CEST) – UCB, a global biopharmaceutical company, today announced that it will present new data on bimekizumab at the 32nd European Academy of Dermatology and Venereology (EADV) Congress, October 11–14th in Berlin, Germany. Data will be presented in four oral presentations and 14 posters across a range of diseases including hidradenitis suppurativa (HS), psoriasis and psoriatic arthritis (PsA). Three oral presentations will share bimekizumab data in hidradenitis suppurativa including the first presentation of pooled analyses from the two Phase 3 studies.

“We are proud to share new clinically relevant and patient-focused data at the upcoming EADV Congress. Our expanding dermatology portfolio highlights our continued dedication to addressing unmet needs and to advancing treatment options for people with chronic inflammatory skin diseases,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

- **In moderate to severe psoriasis**, long-term three-year pooled analyses from five Phase 3/3b bimekizumab studies in moderate to severe plaque psoriasis will be presented, including the evaluation of maintenance of response in Week 16 responders, and the clinical response in high-impact areas. In addition, there will be the first presentations of bimekizumab real-world data from Germany.
- **In moderate to severe HS**, three oral presentations will share the first analysis of pooled data from the two Phase 3 studies, BE HEARD I and BE HEARD II, evaluating bimekizumab in the treatment of moderate to severe HS, including an assessment of disease severity over 48 weeks, as measured by the International HS Severity Score System (IHS4), as well as the response across weight and body mass index subgroups.
- **In PsA**, one oral presentation will present 52-week data from the bimekizumab Phase 3 BE OPTIMAL and BE COMPLETE studies and the open-label extension, BE VITAL.

In the European Union, bimekizumab is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy, for the treatment of adults with active psoriatic arthritis and for the treatment of adults with active axSpA, including non-radiographic axSpA and ankylosing spondylitis, also known as radiographic axSpA.¹ The label information may differ in other countries where approved. Please check local prescribing information. The efficacy and safety of bimekizumab in HS have not been established, and it is not approved for use in this indication by any regulatory authority worldwide.

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.





UCB data presentations at EADV 2023

Bimekizumab abstracts

Hidradenitis Suppurativa

- Bimekizumab efficacy and safety in patients with moderate to severe hidradenitis suppurativa: Analysis of pooled data from BE HEARD I and II phase 3, randomised, double-blind, placebo-controlled, multicenter studies
Zouboulis CC, Gottlieb AB, Forman S, Weisman J, Szepietowski JC, Prens EP, Fujita H, Dokhe P, Muller E, Madden C, Roller R, Kimball AB
Oral Presentation: Thursday, October 12, 14:45 – 15:45 (CEST)
- IHS4 outcomes with bimekizumab in patients with moderate to severe hidradenitis suppurativa: Pooled results from the BE HEARD I and II phase 3 trials
Zouboulis CC, Kirby JS, Tzellos T, Khattry S, Alavi A, Podda M, del Marmol V, Spelman L, Roller R, Joshi P, Davis L, Pansar I, Frew JW
Oral Presentation: Thursday, October 12, 15:15 – 15:25 (CEST)
- Bimekizumab efficacy across weight and BMI based subgroups in patients with moderate to severe hidradenitis suppurativa: 48-week pooled results from the randomised, double-blind, placebo-controlled, multicentre BE HEARD I and II phase 3 trials
Garg A, Lev-Tov H, Naik HB, Hampton P, Martorell A, Fernández-Peñas P, Tilt N, Madden C, Sidhu J, Dokhe P, Benhadou F
Oral Presentation: Thursday, October 12, 14:25 – 14:35 (CEST)
- Bimekizumab response maintenance to 48 weeks in patients with moderate to severe hidradenitis suppurativa: Pooled responder analysis from the phase 3, double-blind, placebo-controlled, randomised clinical trials BE HEARD I and II
Ingram JR, Porter M, Chovatiya R, Giamarellos-Bourboulis EJ, Bechara FG, Fujita H, Gulliver W, Muller E, Bari M, Roller R, Byerly R, Kirby JS
Poster: P0086
- Bimekizumab safety in patients with moderate to severe hidradenitis suppurativa: Analysis of pooled data from the BE HEARD I and II phase 3, randomised, double-blind, placebo-controlled, multicentre studies
Bechara FG, Hamzavi I, Anadkat MJ, Pinter A, Reguiai Z, Fujita H, Albrecht L, Dokhe P, Joshi P, Roller R, Deherder D, Peterson L, Jemec G
Poster: P0087
- Bimekizumab efficacy by prior biologic treatment in patients with moderate to severe hidradenitis suppurativa: 48-week pooled data from the randomised, double-blind, placebo-controlled, multicentre BE HEARD I and II phase 3 trials

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.

Sayed C, Shi VY, Hsiao J, Kokolakis G, Kirby B, Piguet V, Davis L, Bari M, Madden C, Knowles S, Prens EP
Poster: P0132

Psoriatic Arthritis

- Bimekizumab efficacy and safety in patients with active psoriatic arthritis and psoriasis: 52-week results from two phase 3 randomised, placebo-controlled studies
Thaçi D, Asahina A, Lebwohl M, McInnes IB, Merola JF, Warren RB, Boehncke W-H, Ink B, Bajracharya R, Coarse J, Gottlieb AB
Oral Presentation: Friday, October 13, 09:00 – 09:10 (CEST)
- Sustained efficacy and safety of bimekizumab in patients with active psoriatic arthritis and prior inadequate response to tumour necrosis factor inhibitors: Results from the phase 3 BE COMPLETE study and its open-label extension up to 1 year
Coates LC, Landewé R, McInnes IB, Mease PJ, Ritchlin CT, Tanaka Y, Asahina A, Behrens F, Gladman DD, Gossec L, Gottlieb AB, Warren RB, Ink B, Bajracharya R, Coarse J, Merola JF
Poster: P0704
- A matching-adjusted indirect comparison of the efficacy of bimekizumab and guselkumab at 52 weeks for the treatment of psoriatic arthritis
Warren RB, Mease PJ, Nash P, Willems D, Taieb V, Eells J, McInnes IB, Grouin JM, Lyris N
Poster: P0757

Psoriasis

- Bimekizumab 3-year safety and tolerability in moderate to severe plaque psoriasis: Long-term pooled analysis from five phase 3/3b trials
Lebwohl M, Strober B, Langley RG, Okubo Y, Foley P, Warren RB, Peterson L, Cross N, Wiegatz S, Deherder D, Thaçi D
Poster: P2315
- Bimekizumab response through 3 years in patients with plaque psoriasis who stopped and re-started treatment
Costanzo A, Papp K, Griffiths CEM, Rosmarin D, Puig L, Han G, Tilt N, Wixted K, Szilagyi B, Lambert J, Blauvelt A
Poster: P2511
- Bimekizumab 3-year efficacy in high-impact areas in moderate to severe plaque psoriasis: Pooled results from five phase 3/3b trials
Merola JF, Conrad C, Hampton P, Lambert J, Gottlieb AB, Tilt N, Cross N, Wiegatz S, Gooderham M
Poster: P2547

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.

- Bimekizumab 3-year maintenance of response in Week 16 responders with moderate to severe plaque psoriasis: Results from five phase 3/3b trials
Thaçi D, Armstrong A, Gordon KB, Blauvelt A, Paul C, Boehncke WH, Wang M, Szilagyi B, Hoepken B, Lambert J, Lebwohl M
Poster: P2540
- Bimekizumab efficacy through 144 weeks in moderate to severe plaque psoriasis: Patient-reported outcomes from BE RADIANT
Gottlieb AB, Gisondi P, Sator P, Cather J, Feldman SR, Belinchón I, Vender R, Warham R, Szilagyi B, Lambert J, Augustin M
Poster: P2582
- Bimekizumab impact on cardiovascular inflammation markers in moderate to severe plaque psoriasis: Results from phase 3 trials
Warren RB, Langley RG, Kokolakis G, Kirby B, Krueger JG, Eyerich K, Davis L, Davies O, Cross N, Deherder D, Strober B
Poster: P2549
- Real-world patient characteristics and prior treatment history of bimekizumab patients in Germany
Zink A, Ramond A, Shang A, Bley R, Kokolakis G
Poster: P2533
- Treatment history and symptom severity in patients with moderate to severe plaque psoriasis being initiated on bimekizumab: Use during the 1st year of routine clinical practice
Asadullah K, Korge B, Pinter A, Heidbrede T, Kumke T, Schlüter K, Fierens F, Quist S, Stavermann T
Poster: P2594

Axial Spondyloarthritis

- Bimekizumab improves key patient reported symptoms of axial spondyloarthritis including spinal pain and fatigue: Results from two phase 3 studies
Mease PJ, Deodhar A, Dougados M, Dubreuil M, Magrey M, Marzo-Ortega H, Rudwaleit M, de la Loge C, Ellis A, Fleurinck C, Oortgiesen M, Taieb V, Gensler LS
Poster: P0288

CIMZIA® (certolizumab pegol) abstracts

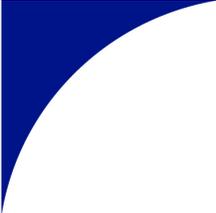
Psoriasis

- Real-world data on the use of certolizumab pegol for the treatment of moderate-to-severe plaque psoriasis: 1-year results from a prospective non-interventional cohort study
Warren RB, Korge B, Sarro DV, Vanhooetghem O, Rodríguez-Cerdeira C, Bianchi L, Perrussel M, Shimizu S, Kadima H, Williams P, Hee J, Pousa ID, Fierens F, Lazaridou E

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.



Poster: P2592

- Real-world data on the 1-year treatment of psoriasis with the use of certolizumab pegol in women of child-bearing potential
Asadullah K, Concetta Fagnoli M, De Simone C, Boyé T, Hillary T, Machovcova A, Makrygeorgou A, Papp K, Flórez Á, Williams P, Pousa ID, Houston N, Fierens F, Papadavid E
Poster: P2590

Disease State abstracts: Psoriasis

- Association of EQ-VAS with treatment benefits and patient-reported benefits in patients with moderate to severe psoriasis – data from the German national psoriasis registry PsoBest
Augustin M, Janke TM, Heidbrede T, Fierens F
Poster: P2596
- Temporal impact of infection-related treatment emergent adverse events on patient-reported outcomes in patients with moderate to severe psoriasis – analysis of the German national registry PsoBest
Augustin M, Janke TM, Heidbrede T, Fierens F
Poster: P2597

Notes to editors:

About certolizumab pegol in the EU/EEA²

In the EU, CIMZIA® (certolizumab pegol) in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active RA in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including MTX, has been inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. Certolizumab pegol in combination with MTX is also indicated for the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs. Certolizumab pegol has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX.

Certolizumab pegol, in combination with MTX, is also indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

Certolizumab pegol is also indicated in the EU for the treatment of adult patients with severe active axial spondyloarthritis (axSpA), comprising:

- Ankylosing spondylitis (AS) – adults with severe active AS who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).
- Axial spondyloarthritis (axSpA) without radiographic evidence of AS – adults with severe active axSpA without radiographic evidence of AS but with objective signs of inflammation by

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.

elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have had an inadequate response to, or are intolerant to NSAIDs.

Certolizumab pegol is also indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Cimzia® (certolizumab pegol) EU/EEA Important Safety Information²

Cimzia® was studied in 4,049 patients with rheumatoid arthritis (RA) in controlled and open label trials for up to 92 months. The commonly reported adverse reactions (1-10%) in clinical trials with certolizumab pegol and post-marketing were viral infections (includes herpes zoster, papillomavirus, influenza), bacterial infections (including abscess), rash, headache (including migraine), asthenia, leukopenia (including lymphopenia, neutropenia), eosinophilic disorder, pain (any sites), pyrexia, sensory abnormalities, hypertension, pruritus (any sites), hepatitis (including hepatic enzyme increase), injection site reactions, and nausea. Serious adverse reactions include sepsis, opportunistic infections, tuberculosis (including miliary, disseminated and extrapulmonary), herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic oedema, cardiomyopathies (includes heart failure), ischemic coronary artery disorders, pancytopenia, hypercoagulation (including thrombophlebitis, pulmonary embolism), cerebrovascular accident, vasculitis, hepatitis/hepatopathy (includes cirrhosis), and renal impairment/nephropathy (includes nephritis). In RA controlled clinical trials, 4.4% of patients discontinued taking certolizumab pegol due to adverse events vs. 2.7% for placebo.

Certolizumab pegol was initially studied in 325 patients with active axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis) in the AS001 clinical study for up to 4 years, which includes a 24-week placebo-controlled phase followed by a 24-week dose-blind period and a 156-week open-label treatment period. Certolizumab pegol was subsequently studied in 317 patients with non-radiographic axial spondyloarthritis in a placebo-controlled study for 52 weeks (AS0006). Certolizumab pegol was also studied in patients with axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis) in a clinical study for up to 96 weeks, which included a 48-week open-label run-in phase (N=736) followed by a 48-week placebo-controlled phase (N=313) for patients in sustained remission (C-OPTIMISE). Certolizumab pegol was also studied in a 96-week open-label study in 89 axSpA patients with a history of documented anterior uveitis flares. In all 4 studies, the safety profile for these patients was consistent with the safety profile in rheumatoid arthritis and previous experience with certolizumab pegol.

Certolizumab pegol was studied in 409 patients with psoriatic arthritis (PsA) in a clinical study for up to 4 years which included a 24-week placebo-controlled phase followed by a 24-week dose-blind period and a 168-week open-label treatment period.

The safety profile for axSpA and PsA patients treated with certolizumab pegol was consistent with the safety profile in RA and previous experience with certolizumab pegol.

Certolizumab pegol was studied in 1112 patients with psoriasis in controlled and open-label studies for up to 3 years. In the Phase III program, the initial and maintenance periods were followed by a 96-week open-label treatment period. The long-term safety profile of certolizumab pegol 400 mg every 2 weeks and certolizumab pegol 200 mg every 2 weeks was generally similar and consistent

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.

with previous experience with certolizumab pegol.

Certolizumab pegol is contraindicated in patients with hypersensitivity to the active substance or any of the excipients, active tuberculosis or other severe infections such as sepsis or opportunistic infections, and moderate to severe heart failure.

Serious infections including sepsis, tuberculosis and opportunistic infections (e.g. histoplasmosis, nocardia, candidiasis) have been reported in patients receiving certolizumab pegol. Some of these events have been fatal. Before initiation of therapy with certolizumab pegol, all patients must be evaluated for both active and inactive (latent) tuberculosis infection. If active tuberculosis is diagnosed prior to or during treatment, certolizumab pegol therapy must not be initiated and must be discontinued. If latent tuberculosis is diagnosed, appropriate anti-tuberculosis therapy must be started before initiating treatment with certolizumab pegol.

Reactivation of hepatitis B has occurred in patients receiving a TNF-antagonist including certolizumab pegol who are chronic carriers of the virus (i.e. surface antigen positive). Some cases have had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with certolizumab pegol. Carriers of HBV who require treatment with certolizumab pegol should be closely monitored and in the case of HBV reactivation Certolizumab pegol should be stopped and effective anti-viral therapy with appropriate supportive treatment should be initiated.

TNF antagonists including certolizumab pegol may increase the risk of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease including multiple sclerosis; of formation of autoantibodies and uncommonly of the development of a lupus-like syndrome; of severe hypersensitivity reactions. If a patient develops any of these adverse reactions, certolizumab pegol should be discontinued and appropriate therapy instituted.

With the current knowledge, a possible risk for the development of lymphomas, leukaemia or other malignancies in patients treated with a TNF antagonist cannot be excluded. Rare cases of neurological disorders, including seizure disorder, neuritis and peripheral neuropathy, have been reported in patients treated with certolizumab pegol.

Adverse reactions of the haematologic system, including medically significant cytopenia, have been reported with certolizumab pegol. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on certolizumab pegol. Consider discontinuation of certolizumab pegol therapy in patients with confirmed significant haematological abnormalities.

The use of certolizumab pegol in combination with anakinra or abatacept is not recommended due to a potential increased risk of serious infections. As no data are available, certolizumab pegol should not be administered concurrently with live vaccines. The 14-day half-life of certolizumab pegol should be taken into consideration if a surgical procedure is planned. A patient who requires surgery while on certolizumab pegol should be closely monitored for infections.

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information.

European SmPC date of revision April 2023. <https://www.ema.europa.eu/en/documents/product->

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.

[information/cimzia-epar-product-information_en.pdf](#) Last Accessed: October 2023

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.³ The therapeutic indications in the European Union are:

- **Plaque psoriasis:** Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.¹
- **Psoriatic arthritis:** Bimekizumab is indicated alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).¹
- **Axial Spondyloarthritis:** Bimekizumab is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs), and for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.¹

BIMZELX® ▼ (bimekizumab) EU/EEA* Important Safety Information¹

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%, 14.6%, 16.3% in plaque psoriasis (PSO), psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA), respectively) and oral candidiasis (7.3%, 2.3%, 3.7% in PSO, PsA and axSpA, respectively). Common adverse reactions ($\geq 1/100$ to $< 1/10$) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, headache, rash, 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 initiated 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. If a patient develops an infection the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy, treatment should be discontinued until the infection resolves. Prior to initiating treatment with bimekizumab, patients should be evaluated for tuberculosis (TB) infection. Bimekizumab should not be given in patients with active TB. Patients receiving bimekizumab should be monitored for signs and symptoms of active TB.

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.

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.

European SmPC date of revision: June 2023.

https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

Last accessed: October 2023.

*EU/EEA means European Union/European Economic Area

▼ *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*

For further information, contact UCB:

Investor Relations

Antje Witte
T +32.2.559.94.14
email antje.witte@ucb.com

Corporate Communications

Laurent Schots
T +32.2.559.92.64
email laurent.schots@ucb.com

Brand Communications

Eimear O'Brien
T +32.2.559.92.71
email eimear.obrien@ucb.com

About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.

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 8,700 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: 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. 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.

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.

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.

References

1. BIMZELX® (bimekizumab) EU Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Last accessed: October 2023.
2. CIMZIA® (certolizumab pegol) EU Summary of Product Characteristics. April 2023. https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf. Last accessed October 2023.
3. Glatt S, Helmer E, Haier B, et al. First-in-human randomized study of bimekizumab, a humanized monoclonal antibody and selective dual inhibitor of IL-17A and IL-17F, in mild psoriasis. *Br J Clin Pharmacol.* 2017;83(5):991–1001.

GL-BK-2300013

Date of preparation: October 2023

© UCB Biopharma SRL, 2023. All rights reserved.