

UCB Showcases Commitment to Advancing Care in Immune-Mediated Inflammatory Diseases with 23 Abstracts at EULAR 2023

- Data to be presented on bimekizumab, CIMZIA[®] (certolizumab pegol), and dapirolizumab pegol
- First presentation of bimekizumab 52-week data from the open-label extension of the Phase 3 BE COMPLETE study in psoriatic arthritis
- New 52-week data evaluating the impact of bimekizumab on peripheral manifestations of axial spondyloarthritis and inflammatory lesions of the sacroiliac joints and spine

Brussels (Belgium), 30th May 2023 (07:00 CET) – UCB, a global biopharmaceutical company, today announced that it will present 23 abstracts across multiple immune-mediated inflammatory diseases at the European Congress of Rheumatology, EULAR 2023, in Milan, Italy, May 31–June 3. The abstracts including data on bimekizumab, CIMZIA[®] (certolizumab pegol) and dapirolizumab pegol have been accepted as five poster tours, eleven poster views and seven abstract book presentations.

“The breadth of data that we are presenting at EULAR 2023 highlight our expanding rheumatology portfolio and enduring effort to advance care for diverse immune-mediated inflammatory conditions,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

The abstracts highlight UCB’s latest research in axial spondyloarthritis (axSpA), psoriasis, psoriatic arthritis (PsA) and systemic lupus erythematosus (SLE) with key data to be shared including:

- Results from the phase 3 BE COMPLETE study and its open-label extension evaluating bimekizumab up to one year in patients with active PsA and prior inadequate response to tumour necrosis factor inhibitors.
- 52-week results from the phase 3 BE MOBILE 1 and BE MOBILE 2 studies in patients with active axSpA evaluating the impact of bimekizumab on inflammatory lesions of the sacroiliac joints and spine as assessed by magnetic resonance imaging (MRI).
- Results from the phase 3 BE MOBILE 1 and BE MOBILE 2 studies evaluating the impact of bimekizumab on the main peripheral manifestations of axSpA, enthesitis and peripheral arthritis, up to week 52.

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- Post hoc analysis of phase 2 clinical data evaluating clinical response of dapirolizumab pegol in subgroups in patients with SLE.

Bimekizumab is not approved for use in ankylosing spondylitis (AS), PsA or non-radiographic axSpA (nr-axSpA) by any regulatory authority worldwide. The safety and efficacy of bimekizumab in AS, PsA and nr-axSpA have not been established.

Dapirolizumab pegol is not approved for use in SLE by any regulatory authority worldwide. The safety and efficacy of dapirolizumab pegol in SLE have not been established.

The following is a guide to the UCB-sponsored data presentations at EULAR 2023:

Bimekizumab abstracts: Psoriatic Arthritis

- 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
POS0231
Poster tour presentation: Friday, June 2, 12:00–13:30 CEST
- Bimekizumab maintained efficacy responses through 52 weeks in biologic disease-modifying antirheumatic drug-naïve patients with psoriatic arthritis who were responders at Week 16: Results from BE OPTIMAL, a phase 3, active-reference study
Tillett W, Merola JF, Tanaka Y, Favalli EG, McGonagle D, Walsh JA, Thaçi D, Ink B, Bajracharya R, Taieb V, Ritchlin CT
POS1534
Poster view presentation: Saturday, June 3, 10:30–11:30 CEST
- Bimekizumab efficacy and safety in biologic DMARD-naïve patients with psoriatic arthritis was consistent with or without methotrexate: 52-week results from the phase 3 active-reference study BE OPTIMAL
McInnes IB, Mease PJ, Tanaka Y, Behrens F, Gossec L, Husni ME, Kristensen LE, Warren RB, Ink B, Bajracharya R, Coarse J, Eells J, Gottlieb AB
POS1537
Poster view presentation: Saturday, June 3, 10:30–11:30 CEST
- Bimekizumab treatment resulted in clinically meaningful improvements in the psoriatic arthritis impact of disease-12 (PsAID-12) scores using pooled results from two phase 3 trials in patients with psoriatic arthritis
Gossec L, Coates LC, Orbai A-M, de Wit M, Lambert J, Ink B, Taieb V, Gladman DD

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POS1533

Poster view presentation: Saturday, June 3, 10:30–11:30 CEST

- Identification of responder and disease activity thresholds for the Psoriatic Arthritis Impact of Disease-12 (PsAID-12) using pooled data from two phase 3 trials of bimekizumab in patients with psoriatic arthritis

Gossec L, Coates LC, Orbai A-M, de Wit M, Pelligra C, Lambert J, Ciaravino V, Ink B, Taieb V, Gladman DD

POS0590-HPR

Poster view presentation: Wednesday, May 31, 15:30–16:30 CEST

- Achievement of increasingly stringent clinical disease control criteria was associated with greater improvements in physical function, pain and fatigue in patients with active psoriatic arthritis: 52-week results from BE OPTIMAL, a phase 3 randomised, placebo-controlled study

Kristensen LE, Coates LC, Mease PJ, Merola JF, Gisondi P, Nash P, Orbai A-M, Tillett W, Ink B, Bajracharya R, Taieb V, Lambert J, Willems D, Walsh JA

AB1100

Abstract book

- Sustained efficacy of bimekizumab treatment assessed using composite measures of disease activity in patients with psoriatic arthritis and prior inadequate response or intolerance 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, Ritchlin CT, Gottlieb AB, Orbai A-M, Warren RB, Ink B, Bajracharya R, Coarse J, Merola JF

AB1099

Abstract book

Bimekizumab abstracts: Axial Spondyloarthritis

- Bimekizumab reduced MRI inflammatory lesions in patients with axial spondyloarthritis: Week 52 results from the BE MOBILE 1 and BE MOBILE 2 phase 3 studies

Baraliakos X, Navarro-Compan V, Poddubnyy D, Dubrueil M, Bennett A, Jans L, Massow U, Fleurinck C, Vaux T, Ellis AM, de Peyrecave N, Maksymowych WP

POS0246

Poster tour presentation: Friday, June 2, 12:00–13:30 CEST

- Resolution of enthesitis and peripheral arthritis with bimekizumab in patients with axial spondyloarthritis: Week 52 results from the BE MOBILE 1 and BE MOBILE 2 phase 3 studies

Ramiro S, Poddubnyy D, Mease PJ, Lopez-Medina C, Fleurinck C, Kim M, Massow U, Taieb V, Wenzel Kragstrup T, McGonagle DG

POS0247

Poster tour presentation: Friday, June 2, 12:00–13:30 CEST

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- Bimekizumab maintained improvements in efficacy endpoints and had a consistent safety profile through 52 weeks in patients with non-radiographic and radiographic axial spondyloarthritis: Results from two parallel phase 3 studies
Baraliakos X, Deodhar A, van der Heijde D, Magrey M, Maksymowych WP, Tomita T, Xu H, Oortgiesen M, Massow U, Fleurinck C, Ellis AM, Vaux T, Shepherd-Smith J, Marten A, Gensler LS
POS1103
Poster view presentation: Friday, June 2, 09:30–10:30 CEST
- Achievement of low disease activity over 52 weeks in patients with active axial spondyloarthritis on bimekizumab treatment: Results from the phase 3 studies BE MOBILE 1 and BE MOBILE 2
Baraliakos X, Ramiro S, Magrey M, Rudwaleit M, Haroon N, Fleurinck C, Massow U, de Peyrecave N, Vaux T, Marzo-Ortega H, Navarro-Compán V
POS1106
Poster view presentation: Friday, June 2, 09:30–10:30 CEST
- Bimekizumab maintained stringent clinical responses through Week 52 in patients with axial spondyloarthritis: Results from the phase 3 studies BE MOBILE 1 and 2
Proft F, van der Heijde D, Baraliakos X, Ermann J, Fleurinck C, Massow U, de Peyrecave N, Taieb V, van Tubergen A, Navarro-Compán V
POS1104
Poster view presentation: Friday, June 2, 09:30–10:30 CEST
- Bimekizumab achieved sustained improvements in efficacy outcomes in patients with axial spondyloarthritis, regardless of prior TNF inhibitor treatment: Week 52 pooled results from two phase 3 studies
Magrey M, van de Sande M, Breban M, Van den Bosch F, Fleurinck C, Massow U, de Peyrecave N, Vaux T, Baraliakos X, Marzo-Ortega H
POS1107
Poster view presentation: Friday, June 2, 09:30–10:30 CEST
- Low uveitis rates in patients with axial spondyloarthritis treated with bimekizumab: Pooled results from phase 2b/3 trials
Brown M, van Gaalen FA, van der Horst-Bruinsma IE, Rudwaleit M, Haroon N, Gensler LS, Deodhar A, Fleurinck C, Marten A, Massow U, Vaux T, White K, de Peyrecave N, Rosenbaum J
POS0668
Poster view presentation: Thursday, June 1, 09:30–10:30 CEST
- Achievement of increasingly stringent clinical response criteria and lower levels of disease activity was associated with greater improvements in physical function and HRQoL in patients with active axial spondyloarthritis: 52-week results from two phase 3 studies on bimekizumab
Magrey M, Deodhar A, Mease PJ, Navarro-Compan V, Ramiro S, Rudwaleit M, de la Loge C, Fleurinck C, Taieb V, Morup MF, Oortgiesen M, Kay J
AB1000
Abstract book

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- Self-reported hidradenitis suppurativa-like skin symptoms in patients with spondyloarthritis: Results from an online survey
Spoorenberg A, Kim M, Pasnar I, Glassner HL
AB1044
Abstract book

Bimekizumab abstract: Psoriatic arthritis and Axial Spondyloarthritis

- Safety profile of bimekizumab at Week 16 in patients with axial spondyloarthritis and psoriatic arthritis: Results from four placebo-controlled phase 3 studies
Poddubnyy D, Gensler LS, Mease PJ, Orbai A-M, Warren RB, Ink B, Massow U, Assudani D, Fleurinck C, Shende V, Shepherd-Smith J, Peterson L, White K, Landewé R
AB0938
Abstract book

Bimekizumab abstract: Psoriasis

- Bimekizumab efficacy in high-impact areas for patients with moderate to severe plaque psoriasis: Pooled results through two years from the BE SURE and BE RADIANT phase 3 trials
Merola J, Gottlieb A, Morita A, Carrascosa JM, Elewski B, Davis L, Wixed K, Wiegatz S, Mrowietz U
AB1089
Abstract book

Certolizumab pegol abstracts: Axial Spondyloarthritis

- Performance analysis of a deep learning algorithm to detect positive SIJ MRI according to the ASAS definition in axSpA patients
Nicolaes J, Tselenti E, Aouad T, Medina CL, Feydy A, Talbot H, Hoepken B, de Peyrecave N, Dougados M
POS0341
Poster tour presentation: Saturday, June 3, 10:00–11:30 CEST
- An exploratory analysis of the potential disconnect between objective inflammatory response and clinical response following certolizumab pegol treatment in patients with active axial spondyloarthritis
Rudwaleit M, Van den Bosch F, Marzo-Ortega H, Navarro-Compan V, Tham R, Kumke T, Bauer L, Kim M, Gensler LS
POS0683
Poster view presentation: Thursday, June 1, 9:30–10:30 CEST
- Comparison of established and new, preliminarily proposed ASAS cut-offs for inflammatory MRI lesions in the sacroiliac joints of axial spondyloarthritis patients and implications for recruitment in clinical studies

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Baraliakos X, Machado PM, Bauer L, Hoepken B, Kim M, Kumke T, Tham R, Rudwaleit M
POS0679

Poster view presentation: Thursday, June 1, 9:30–10:30 CEST

Dapirolizumab Pegol: Systemic Lupus Erythematosus

- Dapirolizumab pegol efficacy by subgroups in patients with systemic lupus erythematosus: A post hoc analysis of phase 2 clinical trial data

Askanase AD, Stach C, Brittain C, Stojan G, Furie RA

POS0115

Poster tour presentation: Thursday, June 1, 12:00–13:30 CEST

Disease: Psoriatic Arthritis

- Real-world usage of biologic disease-modifying antirheumatic drugs in patients with psoriatic arthritis in Sweden

Song J, Abé C, Banefelt J, Rieem Dun A, Willems D, Mørup M, Taieb V, Lindberg I, Welby S

AB1113

Abstract book

Abstracts to be presented at EULAR 2023 Congress are available at: <https://congress.eular.org>
https://congress.eular.org/scientific_programme.cfm

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.^{1,2} 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.^{2,3} The label information may differ in other countries where approved. 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%) (most frequently nasopharyngitis) and oral candidiasis (7.3%). Common adverse reactions ($\geq 1/100$ 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).

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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 May 2022.

Last accessed: May 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.*

About Cimzia® (certolizumab pegol) in the EU/EEA⁴

In the EU, 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. CIMZIA can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

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Certolizumab pegol is also indicated 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 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 Information⁴

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

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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 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.

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

European SmPC date of revision June 2022. https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf Last Accessed: March 2023

About dapirolizumab pegol

Dapirolizumab pegol is an investigational humanized polyethylene glycol (PEG)-conjugated antigen-binding (Fab') fragment lacking a functional Fc domain. Dapirolizumab pegol inhibits CD40L signaling which has been shown to reduce B cell activation and autoantibody production, mitigate type 1 interferon (IFN) secretion, and attenuate T cell and antigen-presenting cell (APC) activation.⁵ Dapirolizumab pegol is presently in Phase 3 clinical development for the treatment of systemic lupus erythematosus (SLE) under a collaboration between UCB and Biogen.⁶

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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 8,700 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

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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.

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References

1. 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.
2. BIMZELX® (bimekizumab) EU Summary of Product Characteristics, May 2023. Available at: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Accessed on May 2023.
3. BIMZELX® (bimekizumab) GB Summary of Product Characteristics. Available at: <https://www.medicines.org.uk/emc/product/12834/smpc#qref>. Accessed on May 2023.
4. CIMZIA® (certolizumab pegol) EU Summary of Product Characteristics. June 2022. https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf. Last accessed May 2023.
5. Furie RA, Bruce IN, Dörner T, et al. Phase 2 randomized, placebo-controlled trial of dapirolizumab pegol in patients with moderate to severe active systemic lupus erythematosus (SLE). *Rheumatology (Oxford).*2021;60(11): 5397–407.

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UCB News

6. ClinGov.gov (NCT04294667). A Study to Evaluate the Efficacy and Safety of Dapirolizumab Pegol in Study Participants With Moderately to Severely Active Systemic Lupus Erythematosus (PHOENYCS GO) 2023 [cited March 2023] Available at: <https://clinicaltrials.gov/ct2/show/NCT04294667>. Last accessed: May 2023

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