UCB News

UCB Reinforces Commitment to Rheumatology with 15 Abstracts including New Late-Breaking Data at ACR Convergence 2022

- Late-breaking 52-week data on investigational bimekizumab in the treatment of adults with active psoriatic arthritis and active axial spondyloarthritis to be presented
- New data on CIMZIA® (certolizumab pegol) and bimekizumab underscore UCB's commitment to innovative research in rheumatology

Brussels (Belgium), 8th November 2022 (18:00 CET) – UCB, a global biopharmaceutical company, today announced that it will present 15 abstracts across its rheumatology portfolio at ACR Convergence 2022 to be held in Philadelphia, November 10–14, 2022. The abstracts, including two with late-breaking data, have been accepted as four oral presentations, eight e-posters, and three 'Ignite Talks' which are five-minute in-person presentations focused on the highest ranked posters at the meeting.

"The breadth of new data we are presenting at ACR Convergence 2022, including the first presentation of bimekizumab 52-week data in psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis, underscore our commitment to address unmet patient needs and to raise standards of care," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

UCB is investigating bimekizumab in psoriatic arthritis (PsA), non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS) also known as radiographic axSpA. The efficacy and safety of bimekizumab in PsA, nr-axSpA and AS have not been established, and it is not approved for use in these indications by any regulatory authority worldwide.

Bimekizumab data highlights

Data evaluating bimekizumab in the treatment of PsA and across the spectrum of axSpA will be shared across three oral presentations, three 'Ignite Talks' and six e-posters.

One oral presentation and one 'Ignite Talk' will detail late-breaking 52-week data from the bimekizumab studies. The oral presentation will present results from the Phase 3 BE OPTIMAL study evaluating bimekizumab in patients with active PsA who were biologic naïve. The 'Ignite Talk' will share data from the Phase 3 BE MOBILE 1 and BE MOBILE 2 studies evaluating bimekizumab in the treatment of nr-axSpA and AS, respectively.

GL-N-BK-axSpA-2200107

Date of preparation: November 2022

A second oral presentation will share data from the Phase 3 BE COMPLETE study, evaluating bimekizumab in the treatment of active PsA in patients with a previous inadequate response or intolerance to Tumor Necrosis Factor Inhibitors (TNFi-IR). A third oral presentation will share 24-week data from the Phase 3 BE MOBILE 1 study evaluating bimekizumab in nr-axSpA.

In addition, 24-week data from the BE MOBILE 2 study evaluating bimekizumab in the treatment of AS and key patient reported outcomes from the Phase 3 BE MOBILE 1 and BE MOBILE 2 studies will be presented in two 'Ignite Talks'.

CIMZIA® (certolizumab pegol) data highlights
Data evaluating certolizumab pegol in the treatment of active axSpA will also be shared across one oral presentation and two e-posters. The oral presentation will detail an exploratory analysis which aims to evaluate the relationship between objective signs of inflammation and clinical outcomes following 12 weeks of certolizumab pegol treatment in patients with active axSpA.

The following is a guide to the UCB-sponsored data presentations at ACR Convergence 2022:

Bimekizumab abstracts: *Psoriatic Arthritis*

- Bimekizumab Treatment in Biologic DMARD-Naïve Patients with Active Psoriatic Arthritis: 52-Week Efficacy and Safety Results from a Phase 3, Randomized, Placebo-Controlled, Active Reference Study
  C. Ritchlin, L. C. Coates, I. McInnes, P. J. Mease, J. Merola, Y. Tanaka, A. Asahina, L. Gossec, A. Gottlieb, D. Thaçi, B. Ink, D. Assudani, R. Bajracharya, V. Shende, J. Coarse, R. Landewé
  #L02
  Oral presentation: Monday, November 14, 9:15am – 9:25am (ET)

- Bimekizumab Treatment in Patients with Active Psoriatic Arthritis and Inadequate Response to Tumor Necrosis Factor Inhibitors: 16-week Efficacy and Safety from a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study
  J. Merola, R. Landewé, I.B. McInnes, P.J. Mease, C. Ritchlin, Y. Tanaka, A. Asahina, F. Behrens, D. Gladman, L. Gossec, R. Warren, B. Ink, D. Assudani, R. Bajracharya, J. Coarse, L. Coates
  #1599
  Oral presentation: Sunday, November 13, 3:30pm – 3:40pm (ET)

- Bimekizumab Treatment Improves Health-Related Quality of Life in Biologic DMARD-Naïve and TNFi-IR Patients with Active PsA: Pooled 16-Week Results From two Phase 3 Randomized, Placebo-Controlled Studies
  D. Gladman, L.E. Kristensen, D. Thaçi, P. Gisondi, L. Gossec, M.E. Husni, A. Gottlieb, H. Dobashi, B. Ink, D. Assudani, R. Bajracharya, J. Coarse, J. Lambert, W. Tillett
  #2122
  e-Poster: Monday, November 14, 1:00pm – 3:00pm (ET)

GL-N-BK-axSpA-2200107

Date of preparation: November 2022

- Bimekizumab Improvements in Efficacy on Disease Activity Assessed via Composite Endpoints in Biologic DMARD-naïve and TNFi-IR Patients with Active PsA: Pooled 16-Week Results from Phase 3 Randomized, Placebo-Controlled Studies
  P.J. Mease, L. Coates, R. Landewé, I.B. McInnes, C. Ritchlin, T. Atsumi, F. Behrens, D. Gladman, L. Gossec, P. Nash, B. Ink, D. Assudani, R. Bajracharya, J. Coarse, A.R. Prickett, A.B. Gottlieb
  # 2117
  e-Poster: Monday, November 14, 1:00pm – 3:00pm (ET)

- Bimekizumab Treatment Results in Improvements in Fatigue and Pain in Biologic DMARD-Naïve or TNFi-IR Patients with Active Psoriatic Arthritis: Pooled 16- Week Results from Two Phase 3 Randomized, Placebo-Controlled Studies
  M.E. Husni, P.J. Mease, J. Merola, F. Behrens, E.G. Favalli, D. McGonagle, W. Tillett, S. Tsuji, B. Ink, D. Assudani, R. Bajracharya, J. Coarse, J. Lambert, L. Gossec
  #2119
  e-Poster: Monday, November 14, 1:00pm – 3:00pm (ET)

- Achieving Increasingly Stringent Clinical Disease Control Criteria is Associated with Greater Improvements in Patient-Centric Measures of Physical Function and Pain in Patients with Active PsA: 16-Week Results from Two Phase 3 Randomized, Placebo-Controlled Studies
  J. Walsh, L. Coates, P.J. Mease, J. Merola, P. Nash, A. Ogdie, W. Tillett, P. Gisondi, B. Ink, D. Assudani, R. Bajracharya, J. Lambert, V. Taieb, D. Willems, L.E. Kristensen
  #2118
  e-Poster: Monday, November 14, 1:00pm – 3:00pm (ET)

Bimekizumab abstracts: ***Axial Spondyloarthritis***

- Bimekizumab Maintains Improvements in Efficacy Endpoints and has a Consistent Safety Profile Through 52 Weeks in Patients with Non-Radiographic Axial Spondyloarthritis and Ankylosing Spondylitis: Results from Two Parallel Phase 3 Studies
  X. Baraliakos, A. Deodhar, D. van der Heijde, M. Magrey, W. Maksymowych, T. Tomita, H. Xu, M. Oortgiesen, U. Massow, C. Fleurinck, A. M. Ellis, T. Vaux, J. Shepherd-Smith, A. Marten, L. S. Gensler
  #L14
  Ignite Talk: Monday, November 14, 2:35pm – 2:40pm (ET)

- Bimekizumab Improves Signs and Symptoms, Including Inflammation, in Patients with Active Non-Radiographic Axial Spondyloarthritis: 24-Week Efficacy & Safety from a Phase 3, Multicenter, Randomized, Placebo-Controlled Study
  A. Deodhar, D. van der Heijde, L. Gensler, H. Xu, K. Gaffney, H. Dobashi, W.P. Maksymowych, M. Rudwaleit, M. Magrey, D. Elewaut, M. Oortgiesen, C. Fleurinck, N. de Peyrecave, A. Ellis, T. Vaux, J. Shepherd-Smith, X. Baraliakos
  #0544
  Oral presentation: Saturday, November 12, 5:00pm – 5.10pm (ET)

GL-N-BK-axSpA-2200107

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- Bimekizumab Improves Signs and Symptoms, Including Inflammation, in Patients with Active Ankylosing Spondylitis: 24-Week Efficacy & Safety From a Phase 3, Multicenter, Randomized, Placebo Controlled Study
  D. van der Heijde, X. Baraliakos, M. Dougados, M. Brown, D. Poddubnyy, F. van den Bosch, N. Haroon, H. Xu, T. Tomita, L. Gensler, M. Oortgiesen, C. Fleurinck, N. de Peyrecave, T. Vaux, A Marten, A. Deodhar
  #0411
  Ignite Talk: Sunday, November 13, 9:10am – 9.15am (ET)

- Bimekizumab Improves Key Patient Reported Symptoms of Axial Spondyloarthritis Including Spinal Pain and Fatigue: Results from Two Phase 3 Studies
  P.J. Mease, A. Deodhar, M. Dougados, M. Dubreuil, M. Magrey, H. Marzo-Ortega, M. Rudwaleit, C. de la Loge, A. Ellis, C. Fleurinck, M. Oortgiesen, V. Taieb, L. Gensler
  #0409
  Ignite Talk: Sunday, November 13, 9:00am – 9:05am (ET)

- Bimekizumab Improves Physical Function and Health-Related Quality of Life in Patients with Axial Spondyloarthritis: Results From Two Phase 3 Studies
  M. Dubreuil, K. Gaffney, L. Gensler, J. Kay, V. Navarro-Compán, C. de la Loge, A. Ellis, C. Fleurinck, M. Oortgiesen, V. Taieb, A. Deodhar
  #0412
  e-Poster: Saturday, November 12, 1:00pm – 3:00pm (ET)

- Achieving Increasingly Stringent Clinical Response Criteria & Lower Levels Of Disease Activity is Associated With Greater Improvements In Physical Function And HRQoL in Patients With Active Axial Spondyloarthritis: 16-Week Results From Two Phase 3 Randomized, Placebo-Controlled Studies
  M. Magrey, A. Deodhar, P.J. Mease, V. Navarro-Compán, S. Ramiro, M. Rudwaleit, C. de la Loge, C. Fleurinck, V. Taieb, M.F. Mørup, M. Oortgiesen, J. Kay
  #0410
  e-Poster: Saturday, November 12, 1:00pm – 3:00pm (ET)

CIMZIA® (certolizumab pegol) abstracts: ***Axial Spondyloarthritis***

- An Exploratory Analysis of the Potential Disconnect Between Objective Inflammatory Response and Clinical Response following Certolizumab Pegol Treatment in Patients with Active Axial Spondyloarthritis
  M. Rudwaleit, F. van den Bosch, H. Marzo-Ortega, V. Navarro-Compán, R. Tham, T. Kumke, L. Bauer, M. Kim, L. Gensler
  #0543
  Oral presentation: Saturday, November 12, 4:45pm – 4:55pm (ET)

- Long-Term Clinical Outcomes of Certolizumab Pegol Treatment in Patients with Active Non-Radiographic Axial Spondyloarthritis Stratified by Baseline MRI and C-Reactive Protein Status

GL-N-BK-axSpA-2200107

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P.C. Robinson, W.P. Maksymowych, L. Gensler, M. Rudwaleit, B. Hoepken, L. Bauer, T. Kumke, M. Kim, A. Deodhar
#0408
e-Poster: Saturday, November 12, 1:00pm – 3:00pm (ET)

- 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
  X. Baraliakos, P. Machado, L. Bauer, B. Hoepken, M. Kim, T. Kumke, R. Tham, M. Rudwaleit
  #1010
  e-Poster: Sunday, November 13, 9:00am – 10:30am (ET)

Abstracts to be presented at ACR Convergence 2022 are available at ACR Convergence 2022 Archives - ACR Meeting Abstracts (acrabstrats.org)

Notes to editors:

About BE OPTIMAL

BE OPTIMAL was a randomized, multicenter, double-blind, placebo-controlled, active reference (adalimumab), parallel-group, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in the treatment of adult patients with active psoriatic arthritis, who are biologic disease-modifying anti-rheumatic drug naïve. For additional details on the study, visit BE OPTIMAL on clinicaltrials.gov.[1]

About BE COMPLETE

BE COMPLETE was a randomized, multicenter, double-blind, placebo-controlled, parallel-group, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in adults with active psoriatic arthritis and an inadequate response to tumor necrosis factor-alpha inhibitors (TNFαi). All enrolled study participants had a history of inadequate response (lack of efficacy after at least three months of therapy at an approved dose) or intolerance to treatment with one or two TNFαi for either psoriatic arthritis or psoriasis. For additional details on the study, visit BE COMPLETE on clinicaltrials.gov.[2]

About BE MOBILE 1

BE MOBILE 1 was a randomized, multicenter, double-blind, placebo-controlled, parallel-group, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in the treatment of adult patients with active nr-axSpA. For additional details on the study, visit BE MOBILE 1 on clinicaltrials.gov.[3]

About BE MOBILE 2

BE MOBILE 2 was a randomized, multicenter, double-blind, placebo-controlled, parallel-group, Phase 3 study designed to evaluate the efficacy and safety of bimekizumab in the treatment of adult patients with active AS. For additional details on the study, visit BE MOBILE 2 on clinicaltrials.gov.[4]

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About CIMZIA® in the U.S.[5]
CIMZIA® is the only Fc-free, PEGylated anti-TNF (Tumor Necrosis Factor). CIMZIA has a high affinity for human TNF-alpha, selectively neutralizing the pathophysiological effects of TNF-alpha.

CIMZIA is also indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), adults with active psoriatic arthritis (PsA), adults with active ankylosing spondylitis (AS), and adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

CIMZIA is indicated for the treatment of moderate to severe plaque psoriasis (PSO) in adults who are candidates for systemic therapy or phototherapy.

In addition, CIMZIA is indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. See important safety information including risk of serious bacterial, viral and fungal infections and tuberculosis below.

IMPORTANT SAFETY INFORMATION about CIMZIA in the U.S.

CONTRAINDICATIONS

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria.

SERIOUS INFECTIONS
Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue CIMZIA if a patient develops a serious infection or sepsis.

Reported infections include:

- Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before CIMZIA use and during therapy. Initiate treatment for latent TB prior to CIMZIA use.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
- Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.

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Carefully consider the risks and benefits of treatment with CIMZIA prior to initiating therapy in the following patients: with chronic or recurrent infection; who have been exposed to TB; with a history of opportunistic infection; who resided in or traveled in regions where mycoses are endemic; with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start CIMZIA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

- Consider the risks and benefits of CIMZIA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among CIMZIA-treated patients compared to control patients.
- In CIMZIA clinical trials, there was an approximately 2-fold higher rate of lymphoma than expected in the general U.S. population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk of lymphoma than the general population.
- Malignancies, some fatal, have been reported among children, adolescents, and young adults being treated with TNF blockers. Approximately half of the cases were lymphoma, while the rest were other types of malignancies, including rare types associated with immunosuppression and malignancies not usually seen in this patient population.
- Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including CIMZIA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treating with CIMZIA in these patient types.
- Cases of acute and chronic leukemia were reported with TNF blocker use.

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HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) has been reported with TNF blockers. Exercise caution and monitor carefully.

HYPERSENSITIVITY

- Angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, and urticaria have been reported following CIMZIA administration. If a serious allergic reaction occurs, stop CIMZIA and institute appropriate therapy. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a plastic derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Test patients for HBV infection before initiating treatment with CIMZIA.
- Exercise caution in patients who are carriers of HBV and monitor them before and during CIMZIA treatment.
- Discontinue CIMZIA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming CIMZIA after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including CIMZIA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, seizure disorder, optic neuritis, peripheral neuropathy, and Guillain-Barré syndrome.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with CIMZIA.
- Consider stopping CIMZIA if significant hematologic abnormalities occur.

DRUG INTERACTIONS

- Do not use CIMZIA in combination with other biological DMARDS.

AUTOIMMUNITY

- Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

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IMMUNIZATIONS

- Patients on CIMZIA should not receive live or live-attenuated vaccines.

ADVERSE REACTIONS

- The most common adverse reactions in CIMZIA clinical trials (≥8%) were: upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

For full prescribing information, please visit
https://www.ucb.com/_up/ucb_com_products/documents/Cimzia_09_11_2019_en.pdf

CIMZIA® is a registered trademark of the UCB Group of Companies.

About certolizumab pegol in the EU/EEA[6]
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 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 Information[6]
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

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(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 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.

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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 June 2022. https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf Last Accessed November 2022

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.[7,8] 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 systemic therapy.[8,9] The label information may differ in other countries. Please check local prescribing information. 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 (FDA).

GL-N-BK-axSpA-2200107

Date of preparation: November 2022

UCB News

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 May 2022.

Last accessed: November 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

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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.

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