UCB News

EULAR 2021: New Data from UCB's Rheumatology Portfolio Demonstrates Real World Value for Patients with axSpA, PsA, and Women of Childbearing Age

- Patients with axial spondyloarthritis (axSpA), who achieve sustained remission, benefit from continued CIMZIA® (certolizumab pegol) treatment either at the full or reduced maintenance dose, a post-hoc analysis of the C-OPTIMISE study confirms
- Further information for healthcare providers considering certolizumab pegol treatment, if clinically needed, for their patients who are women of childbearing age, is being presented from one of the largest cohorts of prospective pregnancies with known outcomes in patients with axSpA, Crohn's disease (CD), psoriatic arthritis (PsA), psoriasis (PSO) and rheumatoid arthritis (RA)
- Long-term safety, efficacy and patient-reported outcomes and quality of life data on UCB's investigational IL-17A and IL-17F inhibitor, bimekizumab, show its potential to make a meaningful difference for people living with ankylosing spondylitis (AS) and PsA

Brussels, Belgium – June 1, 2021, 7:00 CET – UCB, a global biopharmaceutical company, today announced that it will present new data for its Fc-free anti-TNF, CIMZIA® (certolizumab pegol), and its investigational IL-17A and IL-17F inhibitor, bimekizumab, at the European Congress of Rheumatology (EULAR) 2021 on June 2-5, 2021. A total of seven abstracts were accepted for this year's E-Congress, all of which highlight UCB's dedication to innovation in rheumatology and ongoing commitment to address unmet patient needs. Three of the seven abstracts will be presented as posters with guided narrations and live Q&As.

"The information we are presenting at EULAR captures our innovative research in rheumatology and sets us up for a promising future. This important meeting gives us the opportunity to connect our science and innovation to the gaps and barriers that exist in the rheumatology patient journeys," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

CIMZIA (certolizumab pegol) Data Highlights

Certolizumab pegol data include a post-hoc analysis of the Phase 3b C-OPTIMISE study in axSpA. The analysis evaluated disease activity and clinical markers of inflammation in patients who did not experience a disease flare following randomization to certolizumab pegol full maintenance dose (200 mg every two weeks [Q2W]), certolizumab pegol reduced maintenance dose (200 mg every four weeks [Q4W]) or placebo during weeks 48–96 of C-OPTIMISE.[1] The analysis identified consistently higher disease activity and increases in serologic and inflammatory biomarkers in placebo-randomized patients who did not experience a flare during weeks 48-96 of C-OPTIMISE, compared to those who remained on certolizumab pegol.[1] The findings confirm that patients with axSpA who achieve sustained remission benefit from continued certolizumab pegol treatment, either with the full or reduced maintenance dose - over treatment withdrawal.[1]

Additional certolizumab pegol data include two-year results from the Phase 4, open-label C-VIEW study investigating the impact of certolizumab pegol treatment on acute anterior uveitis (AAU) flares in patients with axSpA and a recent history of AAU flares[2], and a post-hoc analysis from an interventional 52-week placebo-controlled study in nr-axSpA (C-axSpAnd) to identify positive magnetic resonance imaging (MRI) or sacroiliac joints and human leukocyte antigen-B27 (HLA-B27) positive carrier at baseline as predictive factors of 52 weeks of clinical response to certolizumab pegol treatment.[3]

UCB will share an analysis that includes more than 1,000 prospective pregnancies with certolizumab pegol exposure in at least the first trimester, representing one of the largest cohorts of pregnancies with known outcomes in patients living with axSpA, CD, PsA, PSO and RA who were exposed to a biologic.[4] No increase in adverse pregnancy outcomes or specific congenital malformations was observed in certolizumab pegol-exposed pregnancies compared to the general population.[5,6] Our data further confirmed the influence of confounding factors, such as specific chronic inflammatory diseases (CIDs), concomitant drugs or comorbidities, on pregnancy outcomes. Taken together, these data offer further information for healthcare providers considering certolizumab pegol treatment, if clinically needed, for their patients who are women of childbearing age.

Bimekizumab Data Highlights

New Phase 2b data from the BE AGILE and BE ACTIVE open-label extension (OLE) studies investigating the long-term safety and efficacy of bimekizumab treatment (160mg Q4W) in patients with AS and PsA, respectively, show that the safety profile of bimekizumab was in line with previous observations.[7,8] There were no new signals, and exposure-adjusted incidence rate decreased with longer exposure.[7,9] In both studies, clinical efficacy outcomes observed at week 48 were sustained through up to three years of treatment.[7,8]

Additional data from the BE AGILE OLE study in patients with active AS treated with bimekizumab over three years demonstrate sustained and consistent efficacy in patient-reported outcomes, in disease activity, physical function, spinal pain, fatigue, morning stiffness and health-related quality of life (ASQoL).[10] Across all reported outcome measures, efficacy was maintained from week 48 to week 144 or 156.[10]

The safety and efficacy of bimekizumab have not been established, and it is not approved by any regulatory authority worldwide.

UCB data presentations at EULAR 2021:

CIMZIA e-Posters with Guided Poster Tour:

- **Disease Activity and Inflammation Following Withdrawal of Certolizumab Pegol Treatment in Axial Spondyloarthritis Patients Who Did Not Experience Flares during the C-OPTIMISE Study**, L. Gensler, X. Baraliakos, L. Bauer, B. Hoepken, T. Kumke, M. Kim, R. Landewé (abstract #POS0229)
- **Pharmacovigilance Pregnancy Data in a Large Population of Patients with Chronic Inflammatory Disease Exposed to Certolizumab Pegol: Pregnancy Outcomes and Confounders**, M. Clowse, R. Fischer-Betz, C. Nelson-Piercy, A. Scheuerle, T. Kumke, B. Lauwerys, R. Kasliwal, F. Förger, Landewé (abstract #POS0022)

CIMZIA e-Posters:

- **Reduction of Anterior Uveitis Flares in Patients with Axial Spondyloarthritis During Certolizumab Pegol Treatment: 96-Week Results from the C-VIEW Study**, I. Van der Horst-Bruinsma, R. Van Bentum, F. Verbraak, T. Rath, B. Hoepken, O. Irvin-Sellers, T. Kumke, L. Bauer, M. Rudwaleit (abstract #POS0897)
- **Predictors of Response in Patients with Non-Radiographic Axial Spondyloarthritis Receiving Certolizumab Pegol in the C-axSpAnd Study**, W. Maksymowych, T. Kumke, S. Auteri, B. Hoepken, L. Bauer, M. Rudwaleit (abstract #POS0896)

Bimekizumab e-Poster with Guided Poster Tour:

- **Bimekizumab Long-Term Safety and Efficacy in Patients with Ankylosing Spondylitis: 3-Year Results from a Phase 2b Study**, D. van der Heijde, A. Deodhar, L. S. Gensler, D. Poddubnyy, A. Kivitz, M. Dougados, N. de Peyrecave, M.Oortgiesen, T. Vaux, C.Fleurinck, X.Baraliakos (abstract #POS0226)

Bimekizumab e-Posters:

- **Bimekizumab Shows Sustained Long-Term Improvements in Patient-Reported Outcomes and Quality of Life in Ankylosing Spondylitis: 3-Year Results from a Phase 2b Study**, X. Baraliakos, M. Dougados, K. Gaffney, R. Sengupta, M. Magrey, N. de Peyrecave, M. Oortgiesen, T. Vaux, C. Fleurinck, V. Ciaravino, A. Deodhar (abstract #POS0919)
- **Bimekizumab Safety and Efficacy in Patients with Psoriatic Arthritis: 3-Year Results from a Phase 2b Open-Label Extension Study**, L. Coates, R. Warren, C. Ritchlin, L. Gossec, J. Merola, D. Assudani, J. Coarse, J. Eells, B. Ink, I. Mcinnes (abstract #POS1022)

About Bimekizumab

Bimekizumab is an investigational humanized monoclonal IgG1 antibody that selectively and directly inhibits both IL-17A and IL-17F, two key cytokines driving inflammatory processes.[11] IL-17F has overlapping biology with IL-17A and drives inflammation independently of IL-17A.[12,13,14,15,16] Selective inhibition of IL-17F in addition to IL-17A suppresses inflammation to a greater extent than IL-17A inhibition alone.[15,16] The safety and efficacy of bimekizumab are being evaluated across multiple disease states as part of a robust clinical program.

About CIMZIA® in the EU/EEA
In the EU, CIMZIA® in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active RA in adult patients inadequately responsive to disease-modifying anti-rheumatic drugs (DMARDs) including MTX.

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

CIMZIA 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.

CIMZIA, 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.

CIMZIA 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.

CIMZIA 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

Date of revision March 2021

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 Cimzia® 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 Cimzia® due to adverse events vs. 2.7% for placebo.

Cimzia 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. Cimzia was subsequently studied in 317 patients with non-radiographic axial spondyloarthritis in a placebo-controlled study for 52 weeks (AS0006). Cimzia 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). In all 3 studies, the safety profile for these patients was consistent with the safety profile in rheumatoid arthritis and previous experience with Cimzia.

Cimzia® 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 Cimzia® was consistent with the safety profile in RA and previous experience with Cimzia®.

Cimzia® 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 Cimzia® 400 mg every 2 weeks and Cimzia® 200 mg every 2 weeks was generally similar and consistent with previous experience with Cimzia.

*EU/EEA means European Union/European Economic Area

Cimzia® 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 Cimzia®. Some of these events have been fatal. Before initiation of therapy with Cimzia®, all patients must be evaluated for both active and inactive (latent) tuberculosis infection. If active tuberculosis is diagnosed prior to or during treatment, Cimzia® 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 Cimzia®.

Reactivation of hepatitis B has occurred in patients receiving a TNF-antagonist including Cimzia® 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 Cimzia®. Carriers of HBV who require treatment with Cimzia® should be closely monitored and in the case of HBV reactivation Cimzia® should be stopped and effective anti-viral therapy with appropriate supportive treatment should be initiated.

TNF antagonists including Cimzia® 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, Cimzia® 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 Cimzia®.

Adverse reactions of the haematologic system, including medically significant cytopenia, have been reported with Cimzia®. 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 Cimzia®. Consider discontinuation of Cimzia® therapy in patients with confirmed significant haematological abnormalities.

The use of Cimzia® in combination with anakinra or abatacept is not recommended due to a potential increased risk of serious infections. As no data are available, Cimzia® should not be administered concurrently with live vaccines. The 14-day half-life of Cimzia® should be taken into consideration if a surgical procedure is planned. A patient who requires surgery while on Cimzia® 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 March 2021.

https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf
Last accessed: May 2021.

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 more than 7,600 people in approximately 40 countries, the company generated revenue of € 5.3 billion in 2020. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

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This press release contains 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, 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 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’ 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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