



## UCB Presents New Data From Rheumatology Portfolio Addressing Unmet Needs in Axial Spondyloarthritis, Psoriatic Arthritis and Lupus at 2019 ACR/ARP

- Oral presentations include data on improvements in clinical and patient-reported outcomes with early CIMZIA (certolizumab pegol) treatment in non-radiographic axial spondyloarthritis, and a reduction in anterior uveitis flares in axial spondyloarthritis patients following one year of treatment with CIMZIA
- Oral presentations of new 48-week data from Phase 2b trials of investigational molecule bimekizumab support the potential value of dual neutralization of IL-17A and IL-17F in psoriatic arthritis and ankylosing spondylitis
- Oral presentation of data from Phase 2b trial of investigational molecule dapirolizumab pegol in patients with moderately to severely active systemic lupus erythematosus

**Brussels, Belgium – 8 November 2019** – UCB, a global biopharmaceutical company, today announced important new rheumatology data being presented on CIMZIA® (certolizumab pegol) and investigational molecules bimekizumab and dapirolizumab pegol at the 2019 American College of Rheumatology and the Association of Rheumatology Professionals (ACR/ARP) Annual Meeting in Atlanta, on November 8-13.

“UCB research presented at the 2019 ACR/ARP congress reflects our leadership in addressing unmet patient needs and providing treatment options that could make a meaningful difference for people living with axSpA, PsA and lupus. The breadth and depth of UCB’s 13 data presentations are intended to improve our understanding of how best to address these serious diseases, which can profoundly impact patients’ lives. UCB continues to deliver on its Patient Value Strategy to connect the unmet needs of patients with innovative science,” said Emmanuel Caeymaex, Head of Immunology and Executive Vice President, Immunology Solutions, UCB.

A post-hoc analysis of the 52-week data from the Phase 3 C-AXSPAND study of CIMZIA will be shared in an oral presentation. The analysis showed that non-radiographic axial spondyloarthritis (nr-axSpA) patients with less than five years of symptoms prior to initiation of CIMZIA treatment had greater improvements across signs and symptoms of disease and quality of life, compared to patients with at least five years of symptoms prior to CIMZIA treatment.<sup>i</sup> These data suggest the value of diagnosing nr-axSpA patients and initiating anti-TNF treatment at an early stage of disease to help improve clinical outcomes. Nr-axSpA is a chronic inflammatory arthritis predominantly affecting the spine and sacroiliac joints, and is a distinct condition within the spondyloarthritis family of chronic inflammatory diseases. In nr-axSpA, there is no definitive radiographic sacroiliitis, though more sensitive magnetic resonance imaging (MRI) testing may detect evidence of active sacroiliitis, visible as inflammation in the sacroiliac joints.<sup>ii</sup>

Earlier this year, CIMZIA became the first and only treatment to gain FDA approval in the U.S. for the treatment of active nr-axSpA with objective signs of inflammation. The approval was based on the C-AXSPAND study, which demonstrated a statistically significant number of patients treated with CIMZIA, in addition to non-biologic background medications (NBBM), reached a Major Improvement in ASDAS (Ankylosing Spondylitis Disease Activity Score) over the 52-week trial, versus placebo plus NBBM.<sup>iii</sup>

Interim 48-week results from a Phase 4 multicenter open-label C-VIEW study will be shared in an oral presentation, showing a significant impact of CIMZIA on reductions in the acute anterior uveitis flare rate in

axial spondyloarthritis (axSpA) patients. C-VIEW is the first study to include a broad population of axSpA patients with active disease, HLA-B27 positivity and a documented history of acute anterior uveitis, the most common extra-articular manifestation in axSpA, affecting up to 40 percent of patients and causing a significant burden.<sup>iv</sup>

Additional presentations focus on patient-reported outcomes for axSpA patients treated with CIMZIA. Positive C-AXSPAND study results show substantial improvements in sleep quality and other clinical outcomes that are important to patients, such as stiffness and fatigue.<sup>v</sup> New research on the impact of treatment with CIMZIA on improvements in work and household productivity as well as social participation for patients with nr-axSpA will be presented.<sup>vi</sup> Additional data from the RAPID-axSpA study showing that CIMZIA treatment in axSpA patients was associated with rapid and sustained reduction in active inflammation, no increase in sclerosis and erosions, and a negligible increase in fatty lesions in the vertebral edges of the spine also will be presented.<sup>vii</sup>

The RAPID-PsA study on CIMZIA in psoriatic arthritis (PsA) evaluated the relationship between PsA disease activity and structural progression over 216 weeks of treatment with CIMZIA. The study showed that it is important for patients to achieve remission or low disease activity to prevent long-term structural damage, particularly in patients at risk of radiographic progression.<sup>viii</sup>

An oral presentation will share efficacy and safety data from the Phase 2b clinical trial of the investigational molecule, dapirolizumab pegol, in patients with moderately to severely active systemic lupus erythematosus (SLE).<sup>ix</sup> The primary objective of the study was to establish a dose-response relationship for dapirolizumab pegol using pre-specified models. The study demonstrated consistent and potentially meaningful improvements for the majority of clinical endpoints in patients treated with dapirolizumab pegol compared with placebo. None of the pre-specified dose-response models could be selected; thus, the primary endpoint was not met. Dapirolizumab pegol demonstrated an acceptable safety profile. UCB and Biogen are collaborating on the development and commercialization of dapirolizumab pegol and have initiated preparations for a Phase 3 program in patients with active SLE despite standard-of-care treatment.

In addition, the company will share 48-week results from the Phase 2b dose finding studies of its investigational pipeline molecule, bimekizumab, in PsA and ankylosing spondylitis (AS) in separate oral presentations. The studies showed that treatment with bimekizumab resulted in achievement of low and/or minimal disease activity in patients with PsA, which were maintained to week 48 as well as sustained improvement in patients with active AS.<sup>x,xi</sup> The AS study showed that significantly more bimekizumab-treated patients achieved ASAS40 (Assessment of SpondyloArthritis International Society 40 percent response) at week 12, compared to placebo, and that these results were sustained to week 48 in the majority of patients. The safety profile was consistent with previous Phase 2 studies, with no new safety findings observed.<sup>xi</sup>

The safety and efficacy of bimekizumab and dapirolizumab pegol have not been established, and they are not approved by any regulatory authority worldwide.

UCB also will be sponsoring a symposium featuring a panel of experts discussing the challenges in recognizing, diagnosing and managing nr-axSpA. A full list of UCB-sponsored data can be found below.

Following is a guide to the UCB-sponsored data presentations:

**UCB Sponsored Non-CME Symposia:**

**A New Horizon in Recognition and Management of Patients With nr-axSpA**, A. Deodhar, W. Maksymowych, L. Gensler, M. Rudwaleit

- Date/time: November 11, 2019: 6:30PM-8:30PM ET
- Location: Marriott Hotel, Rooms A601 and A602

**CIMZIA Oral Presentations:**

**Earlier Treatment of Non-Radiographic Axial Spondyloarthritis with Certolizumab Pegol Results in Improved Clinical and Patient-Reported Outcomes**, J. Kay, L. Gensler, A. Deodhar, W. Maksymowych, N. Haroon, S. Auteri, N. de Peyrecave, T. Kumke, B. Hoepken, L. Bauer, M. Rudwaleit

- Date/time: November 10, 2019: 4:30PM-6:00PM ET
- Location: GWCC Building B, B405-B407

**Reduction of Anterior Uveitis Flares in Patients with Axial Spondyloarthritis Following 1 Year of Treatment with Certolizumab Pegol: 48-Week Interim Results from a 96-Week Open-Label Study**, I. van der Horst-Bruinsma, R. van Bentum, F. D. Verbraak, T. Rath, J. Rosenbaum, M. Misterska-Skóra, B. Hoepken, O. Irvin-Sellers, B. VanLunen, L. Bauer, M. Rudwaleit

- Date/time: November 10, 2019: 4:30PM-6:00PM ET
- Location: GWCC Building B, B405-B407

**CIMZIA Posters:**

**Certolizumab Pegol-Treated Patients with Non-Radiographic Axial Spondyloarthritis Demonstrate Improvements in Sleep Quality and Other Patient Reported Outcomes**, L. Gensler, J. Kay, W. Maksymowych, N. Haroon, L. Bauer, B. Hoepken, N. de Peyrecave, T. Kumke, A. Deodhar

- Date/time: November 11, 2019: 9:00AM-11:00AM ET
- Location: Hall B5

**Certolizumab Pegol Improves Work and Household Productivity and Social Participation Over 1 Year of Treatment in Patients With Non-Radiographic Axial Spondyloarthritis**, A. Deodhar, L. Gensler, J. Kay, W. Maksymowych, N. Haroon, R. Landewé, M. Rudwaleit, S. Hall, L. Bauer, B. Hoepken, N. de Peyrecave, T. Kumke, D. van der Heijde

- Date/time: November 11, 2019: 9:00AM-11:00AM ET
- Location: Hall B5

**Long-Term Certolizumab Pegol Treatment of Axial Spondyloarthritis is Associated with Rapid and Sustained Reduction of Active Inflammation and Minimal Structural Changes in the Spine: 4-Year MRI Results**, X. Baraliakos, S. Kruse, A. Auteri, N. de Peyrecave, T. Nurminen, T. Kumke, B. Hoepken, J. Braun,

- Date/time: November 11, 2019: 9:00AM-11:00AM ET
- Location: Hall B5

**Achievement of Very Low Disease Activity and Remission Treatment Targets is Associated with Reduced Radiographic Progression in Patients with Psoriatic Arthritis Treated with Certolizumab Pegol**, L. Coates, J. F. Merola, A. Kavanaugh, P. Mease, O. Davies, O. Irvin-Sellers, T. Nurminen, D. van der Heijde

- Date/time: November 11, 2019: 9:00AM-11:00AM ET
- Location: Hall B5

**Body Mass Index and Systemic Corticosteroid Use as Indicators of Disease Burden and Their Influence on the Safety Profile of Certolizumab Pegol Across Indications**, A. Blauvelt, J. Curtis, C. Gaujoux-Viala, T. Kvien, W. Sandborn, K. Winthrop, C. Popova, X. Mariette

- Date/time: November 12, 2019: 9:00AM-11:00AM ET
- Location: Hall B5

#### **Bimekizumab Oral Presentations:**

**Dual Neutralization of IL-17A and IL-17F with Bimekizumab in Patients with Active Ankylosing Spondylitis: 48-Week Efficacy and Safety Results From a Phase 2b, Randomized, Blinded, Placebo-Controlled, Dose-Ranging Study**, D. van der Heijde, L. Gensler, A. Deodhar, X. Baraliakos, D. Poddubnyy, A. Kivitz, M. Oortgiesen, D. Baeten, N. Goldammer, J. Coarse, M. Farmer, M. Dougados

- Date/time: November 10, 2019: 4:30PM-6:00PM ET
- Location: GWCC Building B, B405-B407

**Dual Neutralization of IL-17A and IL-17F with Bimekizumab in Patients with Active Psoriatic Arthritis: Disease Activity and Remission in a 48-week Phase 2b, Randomized, Double Blind, Placebo-Controlled, Dose-Ranging Study**, P. Mease, L. Gossec, L. Coates, A. Gottlieb, D. Assudani, J. Coarse, O. Irvin-Sellers, D. Gladman

- Date/time: November 13, 2019: 9:00AM – 10:30AM ET
- Location: GWCC Building B, B309

#### **Dapirolizumab Pegol Oral Presentations:**

**Efficacy and Safety of Dapirolizumab Pegol in Patients with Moderately to Severely Active Systemic Lupus Erythematosus: A Randomized, Placebo-Controlled Study**, R. Furie, I. Bruce, T. Dörner, M. Leon, P. Leszczyński, M. Urowitz, B. Haier, C. Brittain, J. Liu, C. Barbey, C. Stach

- Date/time: November 10, 2019: 4:30PM-6:00PM ET
- Location: GWCC Building A, A411-A412

#### **UCB Sponsored Real-World Data on Chronic Rheumatic Diseases:**

**Gender Differences in Comorbidities and Treatment Utilization among Ankylosing Spondylitis Patients Initiating a Biologic in a Real-World Setting**, A. Sheahan, M. Balamane, E. Lee, R. Suruki

- Date/time: November 10, 2019: 9:00AM-11:00AM ET
- Location: Hall B5

**Inadequate Response within a Year of Biologic and Oral Synthetic DMARD Treatment Initiation among Psoriatic Arthritis Patients in the USA Real-World Setting**, S. Grabich, A. Sheahan, O. Davies, R. Suruki

- Date/time: November 11, 2019: 9:00AM-11:00AM ET
- Location: Hall B5

**Opioid Use Surrounding Diagnosis of Inflammatory Arthritis**, A. Sheahan, V. Sloan, J. Stark, R. Suruki

- Date/time: November 12, 2019: 9:00AM-11:00AM ET
- Location: Hall B5

**About Bimekizumab**

Bimekizumab is an investigational humanized monoclonal IgG1 antibody that potently and selectively neutralizes IL-17A and IL-17F, two key cytokines driving inflammatory processes.<sup>xii</sup> IL-17A and IL-17F have similar pro-inflammatory functions and independently synergize with other inflammatory mediators to drive chronic inflammation and damage across multiple tissues.<sup>xiii,xiv</sup>

**About Dapirolizumab Pegol**

Dapirolizumab pegol is an investigational anti-CD40L pegylated Fab being developed in systemic lupus erythematosus (SLE) jointly by UCB and Biogen. Through interactions with its receptor, CD40, CD40L plays an important role in regulating interactions between T cells and other immune cells, notably B cells and antigen presenting cells, and thus affects several important functional events thought to be involved in autoimmune disease.

**About CIMZIA® in the US**

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

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

In addition, it 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 US****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.**

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.

#### **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 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.

### IMMUNIZATIONS

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

### ADVERSE REACTIONS

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

**For full prescribing information, please visit**

[https://ucb-usa.com/up/ucb\\_usa\\_com\\_kopie/documents/Cimzia\\_PI.pdf](https://ucb-usa.com/up/ucb_usa_com_kopie/documents/Cimzia_PI.pdf)

### 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.

### **About CIMZIA® in Fertility, Pregnancy and Lactation in the EU/EEA**

#### Women of childbearing potential

The use of adequate contraception should be considered for women of childbearing potential. For women planning pregnancy, continued contraception may be considered for 5 months after the last CIMZIA® dose due to its elimination rate, but the need for treatment of the woman should also be taken into account (see below).

#### Pregnancy

Data from more than 500 prospectively collected pregnancies exposed to CIMZIA with known pregnancy outcomes, including more than 400 pregnancies exposed during the first trimester, does not indicate a malformative effect of CIMZIA. However, the available clinical experience is too limited to, with a reasonable certainty, conclude that there is no increased risk associated with CIMZIA administration during pregnancy.

Animal studies using a rodent anti-rat TNF $\alpha$  did not reveal evidence of impaired fertility or harm to the foetus. However, these are insufficient with respect to human reproductive toxicity. Due to its inhibition of TNF $\alpha$ , CIMZIA administered during pregnancy could affect normal immune response in the newborn.

CIMZIA should only be used during pregnancy if clinically needed. Non-clinical studies suggest low or negligible level of placental transfer of a homologue Fab-fragment of certolizumab pegol (no Fc region).

In a clinical study 16 women were treated with certolizumab pegol (200 mg every 2 weeks or 400 mg every 4 weeks) during pregnancy. Certolizumab pegol plasma concentrations measured in 14 infants at birth were Below the Limit of Quantification (BLQ) in 13 samples; one was 0.042  $\mu\text{g/ml}$  with an infant/mother plasma ratio at birth of 0.09%. At Week 4 and Week 8, all infant concentrations were BLQ. The clinical significance of low levels certolizumab pegol for infants is unknown. It is recommended to wait a minimum of 5 months following the mother's last CIMZIA administration during pregnancy before administration of live or live-attenuated vaccines (e.g. BCG vaccine), unless the benefit of the vaccination clearly outweighs the theoretical risk of administration of live or live-attenuated vaccines to the infants.

### Breastfeeding

In a clinical study in 17 lactating women treated with CIMZIA, minimal transfer of certolizumab pegol from plasma to breast milk was observed. The percentage of the maternal certolizumab pegol dose reaching an infant during a 24 hour period was estimated to 0.04% to 0.30%. In addition, since certolizumab pegol is a protein that is degraded in the gastrointestinal tract after oral administration, the absolute bioavailability is expected to be very low in a breastfed infant. Consequently, CIMZIA can be used during breastfeeding.

### Important Safety Information about CIMZIA® in the EU/EEA

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 herpeszoster, papillomavirus, influenza), bacterial infections (including abscess), rash, headache (including migraine), asthaenia, leukopaenia (including lymphopaenia, neutropaenia), 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 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. Monitor patients closely for signs and symptoms of infections including tuberculosis before, during and after treatment with CIMZIA. Treatment with CIMZIA must not be initiated in patients with a clinically important active infection. If an infection develops, monitor carefully and stop CIMZIA until the infection is controlled. 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. Patients should be instructed to seek medical advice if signs/symptoms (e.g., persistent cough, wasting/weight loss, low grade fever, listlessness) suggestive of tuberculosis occur during or after therapy 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 cytopaenia, 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.

CIMZIA was studied in 325 patients with active axial spondyloarthritis (axSpA) and in 409 patients with psoriatic arthritis (PsA) for up to four years. 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 18 months. The safety profile of CIMZIA 400 mg every two weeks and CIMZIA 200 mg every two weeks were generally similar.

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information. European SmPC date of revision June 2019. [https://www.ema.europa.eu/documents/product-information/cimzia-epar-product-information\\_en.pdf](https://www.ema.europa.eu/documents/product-information/cimzia-epar-product-information_en.pdf)

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

**For further information, UCB:**

**Corporate Communications**

Laurent Schots,  
Media Relations, UCB  
T +32.2.559.92.64,  
laurent.schots@ucb.com

**Investor Relations**

Antje Witte,  
Investor Relations, UCB  
T +32.2.559.94.14,  
antje.witte@ucb.com

Isabelle Ghellynck,  
Investor Relations, UCB  
T+32.2.559.9588,  
isabelle.ghellynck@ucb.com

**Brand Communications**

Andrea Levin Christopher,  
Immunology Communications, UCB  
T +1.404.483.7329  
andrea.christopher@ucb.com

## About UCB

UCB, Brussels, Belgium ([www.ucb.com](http://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 in immunology and neurology. With 7,500 people in approximately 40 countries, the company generated revenue of € 4.6 billion in 2018. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB\_news

## Forward looking statements – UCB

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be 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, 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, product liability claims, challenges to patent protection for products or product candidates, 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. UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.

<sup>i</sup> Kay J, et al. Earlier Treatment of Non-Radiographic Axial Spondyloarthritis with Certolizumab Pegol Results in Improved Clinical and Patient-Reported Outcomes. Abstract to be presented at ACR/ARHP 2019, November 8-13 Atlanta, Georgia.

<sup>ii</sup> Khmelinskii N, et al. The Role of Imaging in Diagnosing Axial Spondyloarthritis. *Front Med.* 2018;5:106.

<sup>iii</sup> Deodhar A, et al. A Fifty-Two-Week, Randomized, Placebo-Controlled Trial of Certolizumab Pegol in Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol.* 2019;71(7):1101–1111.

<sup>iv</sup> Van der Horst-Bruinsma I, et al. Reduction of Anterior Uveitis Flares in Patients with Axial Spondyloarthritis Following 1 Year of Treatment with Certolizumab Pegol: 48-Week Interim Results from a 96-Week Open-Label Study. Abstract to be presented at ACR/ARHP 2019, November 8-13 Atlanta, Georgia.

<sup>v</sup> Gensler L, et al. Certolizumab Pegol-Treated Patients with Non-Radiographic Axial Spondyloarthritis Demonstrate Improvements in Sleep Quality and Other Patient Reported Outcomes. Abstract to be presented at ACR/ARHP 2019, November 8-13 Atlanta, Georgia.

<sup>vi</sup> Deodhar A, et al. Certolizumab Pegol Improves Work and Household Productivity and Social Participation Over 1 Year of Treatment in Patients With Non-Radiographic Axial Spondyloarthritis. Abstract to be presented at ACR/ARHP 2019, November 8-13 Atlanta, Georgia.

- <sup>vii</sup> Baraliakos X, et al. Long-Term Certolizumab Pegol Treatment of Axial Spondyloarthritis is Associated with Rapid and Sustained Reduction of Active Inflammation and Minimal Structural Changes in the Spine: 4-Year MRI Results. Abstract to be presented at 2019 ACR/ARP, 8-13 November, Atlanta, GA.
- <sup>viii</sup> Merola J, et al. Achievement of Very Low Disease Activity and Remission Treatment Targets Is Associated with Reduced Radiographic Progression in Patients with Psoriatic Arthritis Treated with Certolizumab Pegol. Abstract to be presented at ACR/ARHP 2019, November 8-13 Atlanta, Georgia.
- <sup>ix</sup> Furie R, et al. Efficacy and Safety of Dapirolizumab Pegol in Patients with Moderately to Severely Active Systemic Lupus Erythematosus: A Randomized, Placebo-Controlled Study. Abstract to be presented at 2019 ACR/ARP, 8-13 November, Atlanta, GA.
- <sup>x</sup> Mease P, et al. Dual Neutralization of IL-17A and IL-17F with Bimekizumab in Patients with Active Psoriatic Arthritis: Disease Activity and Remission in a 48-week Phase 2b, Randomized, Double Blind, Placebo-Controlled, Dose-Ranging Study. Abstract to be presented at ACR/ARHP 2019, November 8-13 Atlanta, Georgia.
- <sup>xi</sup> Van der Heijde D, et al. Dual Neutralization of IL-17A and IL-17F with Bimekizumab in Patients with Active Ankylosing Spondylitis: 48-Week Efficacy and Safety Results From a Phase 2b, Randomized, Blinded, Placebo-Controlled, Dose-Ranging Study. Abstract to be presented at ACR/ARHP 2019, November 8-13 Atlanta, Georgia.
- <sup>xii</sup> 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.
- <sup>xiii</sup> Toy D, Kugler D, Wolfson M, et al. Cutting edge: interleukin 17 signals through a heteromeric receptor complex. *J Immunol Baltim Md 1950*. 2006;177(1):36-39. doi:10.4049/jimmunol.177.1.36
- <sup>xiv</sup> Wright JF, Bennett F, Li B, et al. The human IL-17F/IL-17A heterodimeric cytokine signals through the IL-17RA/IL-17RC receptor complex. *J Immunol Baltim Md 1950*. 2008;181(4):2799-2805. doi:10.4049/jimmunol.181.4.2799