UCB News

UCB showcases advancements in its late stage immunology portfolio through innovative research at 2016 ACR/ARHP Annual Meeting

UCB's pioneering, scientific presence at the 2016 ACR/ARHP Annual Meeting include data on CIMZIA® (certolizumab pegol) across five immunologic disease states and on romosozumab in osteoporosis from multiple Phase 3 studies. Key oral presentations include:

- Seminal findings from EXXELERATE, the first head-to-head superiority study comparing CIMZIA® vs. Humira® (adalimumab) in bio-naïve moderate to severe rheumatoid arthritis (RA) patients, will be presented at a plenary session
- Key romosozumab data from investigational Phase 3 studies in osteoporosis, including the BRIDGE study in men
- New investigational data for CIMZIA®, including: four-year imaging results in ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) patients; efficacy and safety in juvenile idiopathic arthritis (PASCAL study); and two-year Phase 3 C-EARLY® study exploring different dosing strategies in RA patients
- Key results of CRADLE, the first prospective study to specifically examine the level of CIMZIA® transferred from mother's plasma to breast milk

Atlanta, U.S. – November 11, 2016 – UCB, a global biopharmaceutical company focusing on immunology, neurology and bone treatments and research, is proud to announce 16 CIMZIA® (certolizumab pegol) presentations at the 2016 American College of Rheumatology/Association for Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in Washington, D.C. from November 11-16. The results of these presentations offer critical new insights for the use of CIMZIA® to treat patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS), as well as the potential use of CIMZIA® in investigational areas for axial spondyloarthritis (axSpA), non-radiographic (nr-) axSpA, and juvenile idiopathic arthritis (JIA). Additional late-stage pipeline presentations include positive, new investigational data on UCB's romosozumab in osteoporosis.

"UCB is committed to providing meaningful solutions to people living with immunologic disorders. We innovate not only through our science, but with an underlying dedication to developing superior patient insights to ensure that our research and data truly deliver sustained value," said Emmanuel Caeymaex, Head of Immunology and Executive Vice President, Immunology Patient Value Unit, UCB. "Our success with validating CIMZIA® as a meaningful treatment option has been an important part of this heritage, and we're pleased to present data that will help further inform physicians and patients. We're also looking forward to expanding UCB's late-stage portfolio with new data on investigational compounds that will help us move beyond merely addressing symptomology to developing treatments that can potentially be disease modifying."

Seven CIMZIA® abstracts were accepted as oral presentations at the 2016 ACR/ARHP Annual Meeting, validating the relevance of UCB's clinical research program for the rheumatology

community. Notably, the EXXELERATE trial will be presented in an oral plenary session. EXXELERATE is the first head-to-head superiority study comparing the short-term and long-term efficacy, as well as the safety results, between CIMZIA® plus methotrexate (MTX) and Humira® (adalimumab) plus MTX in bio-naïve RA patients across two years. Additional data from EXXELERATE on the efficacy and safety in patients who switched between the two anti-TNF therapies after failure of the primary anti-TNF therapy will be presented as well. Long-term efficacy and safety data from the RAPID-PsA study evaluating the treatment of patients with PsA will be presented in a poster session.

Other key oral presentations include investigational studies examining CIMZIA® in patient populations with significant unmet clinical needs and who are lacking relevant information, such as lactating mothers (the CRADLE study) and pediatric patients with JIA (the PASCAL study), as well as data evaluating CIMZIA® dosing strategies and four-year imaging results from the RAPID-axSpA study.

In the U.S., CIMZIA® is indicated for the treatment of adults with moderately to severely active RA, for the treatment of adults with active PsA and for adults with active AS. In addition, it is indicated for reducing signs and symptoms of Crohn's disease 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 infections and tuberculosis below.[1]

Following is a guide to the UCB-sponsored data presentations

Presentations on CIMZIA® in Approved Indications:

Rheumatoid Arthritis

1. **[2987]: Comparison of Certolizumab Pegol Versus Adalimumab: 2 Year Efficacy and Safety Results from a Superiority, Investigator-Blind, Head-to-Head Study**
   Fleischmann, R. et al.
   - Date/Time: Tuesday November 15; 11:00 AM – 12:30 PM
   - Session Info: ACR Plenary Session, Plenary Session III: Discovery 2016, Hall D

2. **[602]: Efficacy and Safety of Switching Between Certolizumab Pegol and Adalimumab after Primary Anti-TNF Treatment Failure: 2 Year Results from a Randomized, Investigator-Blind, Superiority Head-to-Head Study**
   Fleischmann, R. et al.
   - Date/Time: Sunday November 13; 9:00 AM – 11:00 AM
   - Session Info: ACR Poster Session A, Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy – Poster I, Poster Hall – Hall C

3. **[952]: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study Evaluating Treatment Strategies (Continuation Versus Withdrawal) for Maintaining Low Disease Activity after 1 Year of Certolizumab Pegol in DMARD-Naïve Patients with Early and Progressive, Active RA**
   Weinblatt, M.E. et al.
   - Date/Time: Sunday November 13; 2:30 PM – 4:00 PM

- Session Info: ACR Concurrent Abstract Session, Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy I: Treatment Strategies, Hall E

4. **[594]: Maintenance of Improvements in Patients' Physical Function, Workplace and Household Productivity, and Reduction in Caregiver Burden with 2 Years of Certolizumab Pegol Treatment in DMARD-Naive, Early RA Patients with Severe Progressive Disease**
   Bingham, C.O. et al.
   - Date/Time: Sunday November 13; 9:00 AM – 11:00 AM
   - Session Info: ACR Poster Session A, Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy – Poster I, Poster Hall – Hall C

5. **[595]: Clinical Responses and Improvements in Patient-Reported Outcomes Are Associated with Increased Productivity in the Workplace and at Home in Rheumatoid Arthritis Patients Treated with Certolizumab Pegol**
   Bykerk, V.P. et al.
   - Date/Time: Sunday November 13; 9:00 AM – 11:00 AM
   - Session Info: ACR Poster Session A, Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy – Poster I, Poster Hall – Hall C

6. **[3226]: Maintenance of Clinical Remission and Radiographic Non-Progression with MTX after Completion of 1 Year Initial Treatment with Certolizumab Pegol in Japanese Patients with Early Rheumatoid Arthritis**
   Tanaka, Y. et al.
   - Date/Time: Wednesday November 16; 11:00 AM – 12:30 PM
   - Session Info: ACR Concurrent Abstract Session, Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy V: New Biologics and Remission Induction, Hall E

7. **[2588]: The Real World Comparative Safety of Certolizumab Pegol (CZP) As Compared to Other TNFi in a National US Cohort**
   Harrold, L.R. et al.
   - Date/Time: Tuesday November 15; 9:00 AM – 11:00 AM
   - Session Info: ACR Poster Session C, Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy – Poster III, Poster Hall – Hall C

8. **[1414]: Access to an Active, Interactive Self-Assessment e-Health Platform Improves Patient-Physician Communication in Rheumatoid Arthritis: Results of a Randomized Controlled Trial Including 320 Patients over 1 Year**
   Gossec, L. et al.
   - Date/Time: Monday November 14; 9:00 AM – 11:00 AM
   - Session Info: ACR Poster Session B, Quality Measures and Quality of Care – Poster II, Poster Hall – Hall C

<u>Psoriatic Arthritis</u>

9. **[1724]: The Effect of Certolizumab Pegol on Skin Manifestations of Psoriatic Arthritis over 4 Years of Treatment**
   Khraishi, M. et al.
   - Date/Time: Monday November 14; Poster Display: 8:30 AM – 4:00 PM; Presentation Time: 9:00 AM – 11:00 AM

- Session Info: ACR Poster Session B, Spondylarthropathies and Psoriatic Arthritis – Clinical Aspects and Treatment – Poster II: Psoriatic Arthritis, Poster Hall – Hall C

Multiple Disease States

10. **[1731]: Disease Burden and Impact of Certolizumab Pegol Treatment on Workplace and Household Productivity Across Working Age Rheumatoid Arthritis, Psoriatic Arthritis and Axial Spondyloarthritis Patients**
    Kavanaugh, A.F.
    - Date/Time: Monday November 14; 9:00 AM – 11:00 AM
    - Session Info: ACR Poster Session B, Spondylarthropathies and Psoriatic Arthritis – Clinical Aspects and Treatment – Poster II: Psoriatic Arthritis, Poster Hall – Hall C

Therapeutic Drug Monitoring

11. **[2589]: Comparison of Two Enzyme-Linked Immunosorbent Assays Used for Drug Concentration Monitoring in Psoriatic Arthritis Patients Treated with Certolizumab Pegol**
    Paul, S.
    - Date/Time: Tuesday November 15; 9:00 AM – 11:00 AM
    - Session Info: ACR Poster Session C, Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy – Poster III, Poster Hall – Hall C

12. **[596]: Association Between Plasma Certolizumab Pegol Concentration and Improvement in Disease Activity in Rheumatoid Arthritis and Crohn's Disease**
    Wolbink, G. et al.
    - Date/Time: Sunday November 13; 9:00 AM – 11:00 AM
    - Session Info: ACR Poster Session A, Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy – Poster I, Poster Hall – Hall C

Presentations on Investigational Studies of CIMZIA®

Women of Childbearing Age

13. **[2048]: Evaluating Transfer of Certolizumab Pegol into Breast Milk: Results from a Prospective, Postmarketing, Multicenter Pharmacokinetic Study**
    Clowse, M.E.B. et al.
    - Date/Time: Monday November 14; 4:30 PM – 6:00 PM
    - Session Info: ACR Concurrent Abstract Session, Reproductive Issues in Rheumatic Disorders, 150 A

Axial Spondyloarthritis, including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis

14. **[1042]: Four Year Imaging Outcomes in Patients with Axial Spondyloarthritis Treated with Certolizumab Pegol, Including Patients with Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis**
    van der Heijde, D. et al.
    - Date/Time: Sunday November 13; 4:30 PM – 6:00 PM

- Session Info: ACR Concurrent Abstract Session, Spondylarthropathies and Psoriatic Arthritis – Clinical Aspects and Treatment II: Axial Spondyloarthritis – Treatment, Ballroom B

15. **[687]: Safety and Efficacy of Certolizumab Pegol over 204 Weeks in Patients with Axial Spondyloarthritis, Including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis**
    Deodhar, A. et al.
    - Date/Time: Sunday November 13; Poster Display: 8:30 AM – 4:00 PM; Presentation Time: 9:00 AM – 11:00 AM
    - Session Info: ACR Poster Session A, Spondylarthropathies and Psoriatic Arthritis – Clinical Aspects and Treatment - Poster I: Axial and Peripheral Spondyloarthritis – Clinical Aspects, Imaging and Treatment, Poster Hall – Hall C

Juvenile Idiopathic Arthritis

16. **[947]: A Multi-Center, Open-Label Study to Assess the Pharmacokinetics, Efficacy and Safety of Certolizumab Pegol in Children and Adolescents with Moderately to Severely Active Polyarticular-Course Juvenile Idiopathic Arthritis: Week 24 Results**
    Brunner, H.I. et al.
    - Date/Time: Sunday November 13; 2:30 PM – 4:00 PM
    - Session Info: ACR Concurrent Abstract Session, Pediatric Rheumatology – Clinical and Therapeutic Aspects I: Juvenile Arthritis, Ballroom C

Presentations on UCB's Investigational Pipeline:

Romosozumab

17. **[1023]: Fracture Risk Reduction with Romosozumab: Results of a Phase 3 Study in Postmenopausal Women with Osteoporosis**
    Cosman F. et al.
    - Date/Time: Sunday November 13; 4:30 PM – 6:00 PM
    - Session Info: ACR Concurrent Abstract Session, Osteoporosis and Metabolic Bone Disease – Clinical Aspects and Pathogenesis, 145 A

18. **[1024]: Superior Gains in Bone Mineral Density and Estimated Strength at the Hip for Romosozumab Compared with Teriparatide in Women with Postmenopausal Osteoporosis Transitioning from Bisphosphonate Therapy: Results of a Phase 3, Open-Label Clinical Trial**
    Langdahl B. et al.
    - Date/Time: Sunday November 13; 4:30 PM – 6:00 PM
    - Session Info: ACR Concurrent Abstract Session, Osteoporosis and Metabolic Bone Disease – Clinical Aspects and Pathogenesis, 145 A

19. **[321]: Results of a Phase 3 Clinical Trial to Evaluate the Efficacy and Safety of Romosozumab in Men with Osteoporosis**
    Lewiecki, EM. et al.
    - Date/Time: Sunday November 13; Poster Display: 8:30 AM – 4:00 PM; Presentation Time: 9:00 AM – 11:00 AM

- Session Info: ACR Poster Session A, Osteoporosis and Metabolic Bone Disease – Clinical Aspects and Pathogenesis – Poster, Poster Hall – Hall C

Epratuzumab

20. **[2665]: Epratuzumab Treatment of Patients with Systemic Lupus Erythematosus and Secondary Sjögren's Syndrome: An Exploratory Analysis of Phase 3 Studies**
Gottenberg, J.E. et al.
    - Date/Time: Tuesday November 15; 9:00 AM – 11:00 AM
    - Session Info: ACR Poster Session C, Sjögren's Syndrome – Poster II: Clinical Science, Poster Hall – Hall C

About Romosozumab

Romosozumab is an investigational bone-forming monoclonal agent and is not approved by any regulatory authority for the treatment of osteoporosis. It is designed to work by inhibiting the activity of the protein sclerostin, and has a dual effect on bone, both increasing bone formation and decreasing bone breakdown. Romosozumab is being studied for its potential to reduce the risk of fractures in an extensive global Phase 3 program. This program includes two large fracture trials comparing romosozumab to either placebo or active comparator in more than 10,000 postmenopausal women with osteoporosis. UCB and Amgen are co-developing romosozumab.

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.

Important Safety Information about Cimzia® in the US

Risk of Serious Infections and Malignancy

Patients treated with Cimzia® are at an 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. Cimzia® should be discontinued if a patient develops a serious infection or sepsis. Reported infections include:

- **Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before Cimzia® use and during therapy. Treatment for latent infection should be initiated 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. Empiric anti-fungal therapy should be considered 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.**

The risks and benefits of treatment with Cimzia® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Cimzia®, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

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.

Patients treated with Cimzia® are at an increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death. Opportunistic infections due to bacterial, mycobacterial, invasive fungal, viral, parasitic, or other opportunistic pathogens including aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, legionellosis, listeriosis, pneumocystosis and tuberculosis have been reported with TNF blockers. Patients have frequently presented with disseminated rather than localized disease.

Treatment with Cimzia® should not be initiated in patients with an active infection, including clinically important localized infections. Cimzia® should be discontinued if a patient develops a serious infection or sepsis. Patients greater than 65 years of age, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants (e.g., corticosteroids or methotrexate) may be at a greater risk of infection. Patients who develop a new infection during treatment with Cimzia® should be closely monitored, undergo a prompt and complete diagnostic workup appropriate for immunocompromised patients, and appropriate antimicrobial therapy should be initiated. Appropriate empiric antifungal therapy should also be considered while a diagnostic workup is performed for patients who develop a serious systemic illness and reside or travel in regions where mycoses are endemic.

Malignancies

During controlled and open-labeled portions of Cimzia® studies of Crohn's disease and other diseases, malignancies (excluding non-melanoma skin cancer) were observed at a rate of 0.5 per 100 patient-years among 4,650 Cimzia®-treated patients versus a rate of 0.6 per 100 patient-years among 1,319 placebo-treated patients. In studies of Cimzia® for Crohn's disease and other investigational uses, there was one case of lymphoma among 2,657 Cimzia®-treated patients and one case of Hodgkin lymphoma among 1,319 placebo-treated patients. In Cimzia® RA clinical trials (placebo-controlled and open label), a total of three cases of lymphoma were observed among 2,367 patients. This is approximately 2-fold higher than expected in the general population. Patients with RA, particularly those with highly active disease, are at a higher risk for the development of lymphoma. The potential role of TNF blocker therapy in the development of malignancies is not known.

Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blocking agents (initiation of therapy ≤18 years of age), of which Cimzia® is a member. Approximately half of the cases were lymphoma (including Hodgkin's and non-Hodgkin's lymphoma), while the other cases represented a variety of different malignancies and included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents. Most of the patients were receiving concomitant immunosuppressants.

Cases of acute and chronic leukemia have been reported with TNF-blocker use. Even in the absence of TNF-blocker therapy, patients with RA may be at a higher risk (approximately 2-fold) than the general population for developing leukemia.

Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma that has a very aggressive disease course and is usually fatal, have been reported in patients treated with TNF blockers, including Cimzia®. The majority of reported TNF blocker cases occurred in adolescent and young adult males with Crohn's disease or ulcerative colitis. Almost all of these patients had received treatment with the immunosuppressants azathioprine and/or 6-mercaptopurine (6-MP) concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treatment with Cimzia®, especially in these patient types.

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-antagonists, including CImzia®. Periodic skin examinations are recommended for all patients, particularly those with risk factors for skin cancer.

Heart Failure

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers. Cimzia® has not been formally studied in patients with CHF. Exercise caution when using Cimzia® in patients who have heart failure and monitor them carefully.

Hypersensitivity

Symptoms compatible with hypersensitivity reactions, including angioedema, dyspnea, hypotension, rash, serum sickness, and urticaria, have been reported rarely following Cimzia® administration. Some of these reactions occurred after the first administration of Cimzia®. If such reactions occur, discontinue further administration of Cimzia® and institute appropriate therapy.

Hepatitis B Reactivation

Use of TNF blockers, including Cimzia®, has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. Some cases have been fatal. Test patients for HBV infection before initiating treatment with Cimzia®. Exercise caution in prescribing Cimzia® for patients identified as carriers of HBV, with careful evaluation and monitoring prior to and during treatment. In patients who develop HBV reactivation, discontinue Cimzia® and initiate effective anti-viral therapy with appropriate supportive treatment.

Neurologic Reactions

Use of TNF blockers, including Cimzia®, has been associated with rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disease, including multiple sclerosis, and with peripheral demyelinating disease, including Guillain-Barré syndrome. Rare cases of neurological disorders, including seizure disorder, optic neuritis, and peripheral neuropathy have been reported in patients treated with Cimzia®. Exercise caution in considering the use of Cimzia® in patients with these disorders.

Hematologic Reactions

Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia (e.g., leukopenia, pancytopenia, thrombocytopenia) has been infrequently 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 hematologic abnormalities.

Drug Interactions

An increased risk of serious infections has been seen in clinical trials of other TNF blocking agents used in combination with anakinra or abatacept. Formal drug interaction studies have not been performed with rituximab or natalizumab; however, because of the nature of the adverse events seen with these combinations with TNF blocker therapy, similar toxicities may also result from the use of Cimzia® in these combinations. Therefore, the combination of Cimzia® with anakinra, abatacept, rituximab, or natalizumab is not recommended. Interference with certain coagulation assays has been detected in patients treated with Cimzia®. There is no evidence that Cimzia® therapy has an effect on in vivo coagulation. Cimzia® may cause erroneously elevated aPTT assay results in patients without coagulation abnormalities.

Autoimmunity

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

Immunizations

Do not administer live vaccines or live-attenuated vaccines concurrently with Cimzia®.

Adverse Reactions

In controlled Crohn's clinical trials, the most common adverse events that occurred in ≥5% of Cimzia® patients (n=620) and more frequently than with placebo (n=614) were upper respiratory infection (20% Cimzia®, 13% placebo), urinary tract infection (7% Cimzia®, 6% placebo), and arthralgia (6% Cimzia®, 4% placebo). The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 8% for Cimzia® and 7% for placebo.

In controlled RA clinical trials, the most common adverse events that occurred in ≥3% of patients taking Cimzia® 200 mg every other week with concomitant methotrexate (n=640) and more frequently than with placebo with concomitant methotrexate (n=324) were upper respiratory tract infection (6%

Cimzia®, 2% placebo), headache (5% Cimzia®, 4% placebo), hypertension (5% Cimzia®, 2% placebo), nasopharyngitis (5% Cimzia®, 1% placebo), back pain (4% Cimzia®, 1% placebo), pyrexia (3% Cimzia®, 2% placebo), pharyngitis (3% Cimzia®, 1% placebo), rash (3% Cimzia®, 1% placebo), acute bronchitis (3% Cimzia®, 1% placebo), fatigue (3% Cimzia®, 2% placebo). Hypertensive adverse reactions were observed more frequently in patients receiving Cimzia® than in controls. These adverse reactions occurred more frequently among patients with a baseline history of hypertension and among patients receiving concomitant corticosteroids and non-steroidal anti-inflammatory drugs. Patients receiving Cimzia® 400 mg as monotherapy every 4 weeks in RA controlled clinical trials had similar adverse reactions to those patients receiving Cimzia® 200 mg every other week. The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 5% for Cimzia® and 2.5% for placebo.

The safety profile for patients with Psoriatic Arthritis (PsA) treated with Cimzia® was similar to the safety profile seen in patients with RA and previous experience with Cimzia®.

The safety profile for AS patients treated with Cimzia® was similar to the safety profile seen in patients with RA.

For full prescribing information, please visit www.ucb.com

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

Humira® is a registered trademark of Abbvie.

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 methotrexate or when continued treatment with methotrexate 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.[4]

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 herpes, 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, herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic oedema, cardiomyopathies (includes heart failure), ischemic coronary artery disorders, pancytopaenia, 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 or moderate-to-severe heart failure.

Serious infections including sepsis, tuberculosis and opportunistic infections 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® if infection becomes serious. 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; 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 hematologic system, including medically significant cytopaenia, have been infrequently 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) in a placebo-controlled clinical trial for up to 30 months and in 409 patients with psoriatic arthritis (PsA) in a placebo-controlled clinical trial for up to 30 months. The safety profile for axSpA and PsA patients treated with Cimzia® was consistent with the safety profile in RA and previous experience with Cimzia®.

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information. European SmPC date of revision 15th September 2016. http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

For further information, UCB:

Corporate Communications	**Investor Relations**	**Brand Communications**
France Nivelle, Global Communications, UCB T +32.2.559.9178, france.nivelle@ucb.com	Antje Witte, Investor Relations, UCB T +32.2.559.94.14, antje.witte@ucb.com	Andrea Levin Christopher, Immunology Communications, UCB T +1.404.483.7329 andrea.christopher@ucb.com
Laurent Schots, Media Relations, UCB T+32.2.559.92.64, laurent.schots@ucb.com		

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 7 700 people in approximately 40 countries, the company generated revenue of € 3.9 billion in 2015. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements - UCB

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