The Lancet Publishes First Head-to-Head Study of Cimzia® (certolizumab pegol) and Humira® (adalimumab) in Bio-Naïve Rheumatoid Arthritis Patients

- **While the primary endpoints of superiority of Cimzia® over Humira® were not demonstrated in EXXELERATE, data generated suggest for the first time the benefits of switching to a second anti-TNF (Cimzia® or Humira®), even in primary TNF-failure patients**
- **Comparable safety between Cimzia® and Humira® was observed across two years, including in patients who immediately switched between treatments without a wash-out period**
- **These data were also presented today during the plenary session at the 2016 American College of Rheumatology/Association for Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in Washington, D.C.**

Brussels, Belgium – November 15, 2016, 6:00 PM CET –Today UCB announced that *The Lancet* published full results from EXXELERATE, the first head-to-head superiority study of two treatments in the anti-TNF class. The study compared Cimzia® (certolizumab pegol) plus methotrexate (MTX) to Humira® (adalimumab) plus MTX in adult patients with moderate to severe rheumatoid arthritis (RA) who were inadequate responders to MTX. The study did not meet its primary endpoints for superiority, demonstrating no statistically significant difference in efficacy between Cimzia® and Humira® in combination with MTX in both short-term (12-week) and long-term (2-year) evaluations. However, data from the study demonstrated that switching between these anti-TNFs without a wash-out period was beneficial to some patients.[1]

“We are very pleased that this study has been accepted in *The Lancet*. Prior to EXXELERATE, the body of evidence supporting the use of anti-TNFs after initial anti-TNF treatment failure was limited, as no trials have evaluated the efficacy of an immediate switch from one anti-TNF to another. EXXELERATE, among other important information, provides evidence supporting the treat-to-target approach, emphasizing the importance of clinical decision making three months after initiating therapy. By following this approach, and using a second anti-TNF at Week 12 in the event of inadequate response, clinicians maximize the potential benefit of anti-TNF therapy. This also allows early identification of patients within six months who may not have an adequate response to anti-TNF therapy and who may benefit from a different mode of action,” said Professor Dr. Josef S. Smolen, Department of Medicine 3, Division of Rheumatology, Medical University of Vienna, Austria.

“With EXXELERATE, UCB has taken significant steps to help better inform treatment decisions and bring real world value to patients. EXXELERATE highlights the potential value of switching between Cimzia and Humira after a pre-determined time interval. The ability to make a treatment decision at

three months, as demonstrated in this trial, should benefit patients and minimize resource allocation to an ineffective therapy," said Emmanuel Caeymaex, Head of Immunology and Executive Vice President, Immunology Patient Value Unit, UCB. "Approximately half the initial responders achieved low disease activity within two years, demonstrating that we are developing solutions that enable patients to achieve a desirable level of disease control."

The percentage of patients achieving an ACR20 response at three months was 69.2 percent versus 71.4 percent with Cimzia® and Humira®, respectively, and the percentage of patients achieving a state of low disease activity (LDA) at two years were 35.5 percent versus 33.5 percent, respectively.[1]

In the study, 14.7 percent of patients receiving Cimzia® [n=67] and 12.9 percent of patients receiving Humira® [n=59] did not respond to their initial therapy at three months, with response defined as being in LDA or DAS28(ESR) reduction from Week 12 of ≥1.2. At three months, 65 patients on Cimzia® and 57 patients on Humira® were switched to receive immediate treatment with the other agent without a wash-out period between treatments (patients switching from Humira® to Cimzia® received the loading dose of Cimzia®). Of those patients, 57.9 percent switching to Cimzia® (n=33/57) and 61.5 percent switching to Humira® (n=40/65) responded 12 weeks later by achieving a state of LDA or DAS28 (ESR) reduction from Week 12 of ≥1.2.[1]

The secondary efficacy endpoints between Cimzia® and Humira® showed patients achieving LDA at Weeks 6 (20.5 percent and 18.1 percent), 12 (30.4 percent and 29.7 percent) and 52 (41.6 percent and 38.3 percent) respectively.[1] Change from baseline in HAQ-DI from week 104 was -0.62 and -0.72 and normative physical function (HAQ-DI ≤ 0.2522) was achieved by 20.3% and 22.2% for Cimzia and Humira respectively.

For the study population (n=915), overall safety was similar between agents, including incidence per 100 patient-years of treatment-emergent adverse events (TEAEs, 139.9 and 134.8), serious TEAEs (SAEs, 9.4 and 7.7), and serious infections and infestations (2.2 and 2.0), for Cimzia® and Humira®, respectively (defined by treatment at onset of adverse event). For those patients who switched from one TNF inhibitor to the other, no serious infections or infestations were reported in the 70-day period following treatment switch.[1]

In addition to being published in *The Lancet*, these data were also presented today as an oral presentation during the plenary session at the 2016 ACR/ARHP Annual Meeting in Washington, DC, November 11-16, 2016.

About EXXELERATE[1]

EXXELERATE (NCT01500278) was a Phase 4, 24-month (104-week) randomized, single-blind, parallel-group, head-to-head superiority study. The study was designed to evaluate the short- and long-term efficacy of certolizumab pegol (CZP) compared with adalimumab (ADA), both in combination with methotrexate (MTX), in the treatment of moderate to severe RA patients who have not responded adequately to MTX.

The primary endpoints of the study were the percentage of patients with an ACR20 response at Week 12 (i.e., 20% improvement in tender or swollen joint counts and a 20% improvement in at least three of the other five criteria: patient assessment, physician assessment, pain scale, disability/functional questionnaire, and acute phase reactant) and the percentage of patients who achieved low disease activity (DAS28[ESR] ≤3.2) at Week 104.

Biologic-naïve patients (n=915) with moderate to severe RA and an inadequate response to MTX, were randomly assigned at baseline (Week 0) in a 1:1 ratio to receive either:

- A standard loading dose regimen of CZP 400 mg at Weeks 0, 2 and 4 + MTX, followed by CZP 200 mg Q2W + MTX.
- ADA 40 mg Q2W + MTX, with placebo also given at Weeks 0, 2 and 4 to maintain blinding

MTX dosing was maintained at 15–25 mg/week orally or subcutaneously, with one dose adjustment permitted between Week 12 and Week 52, and a one dose adjustment permitted between Week 52 and Week 104. For patients unable to tolerate MTX at these doses, MTX dose could be reduced to 10 mg/week after Week 12.

At Week 12, patients were categorized as responders, if they achieved low disease activity (LDA), defined as DAS28(ESR) ≤3.2 or had a DAS28(ESR) change from baseline (CFB) reduction ≥1.2.

Patient response at Week 12 determined what treatment they received from this point onwards. Week 12 responders continued with their initial treatment through Week 104. Week 12 non-responders switched treatment, either from CZP to ADA or vice versa, depending on their initial randomised treatment. At Week 24, subjects achieving LDA defined as DAS28(ESR)<or = 3.2 or a DAS28(ESR) reduction of ≥1.2 from Week 12 continued their treatment through to Week 104, but those who did not achieve either of these criteria were withdrawn from the study. Patients and investigators were blinded until week 12 and then only investigators were blinded until week 104.

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, adults with active psoriatic arthritis (PsA), and adults with active ankylosing spondylitis (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 bacterial, viral and fungal infections and tuberculosis below.

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-antaganists, 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

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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

REFERENCES

1. Smolen et al. Head-to-Head Comparison of Certolizumab Pegol versus Adalimumab in Rheumatoid Arthritis: 2-Year Efficacy and Safety Results from the Randomized EXXELERATE Study. Lancet. 2016

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Forward looking statements - UCB
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