Results from CRIB study on CIMZIA® (certolizumab pegol) demonstrate minimal to no placental transfer of drug from mother to infant during third trimester of pregnancy

- First-of-its-kind CRIB study used a sensitive and specific assay designed to detect CIMZIA and found minimal to no placental transfer from mother to infant
- The CRADLE study found minimal to no transfer of CIMZIA through breast milk
- These studies provide complementary information that is important for the management of women of child bearing age with active chronic inflammatory diseases who face limited options during pregnancy and lactation. Adequate disease control is crucial for these women to ensure optimal infant and maternal health and to reduce adverse pregnancy outcomes

Brussels, Belgium – 14 June, 00:10 CEST – UCB today presented results from CRIB, a pharmacokinetic study designed to assess if CIMZIA® (certolizumab pegol) is transferred across the placenta from pregnant women to their infants. The study used a sensitive immunoassay designed specifically to measure CIMZIA and found no measurable levels in 13 out of 14 infant blood samples at birth, and in all infant samples at weeks four and eight after birth. The CRIB study results were presented as an oral presentation at the Annual European Congress of Rheumatology (EULAR) 2017 in Madrid, Spain.[1]

The studies included women with rheumatoid arthritis (RA), psoriatic arthritis (PsA), axial spondyloarthritis (axSpA)/ankylosing spondylitis (AS), and Crohn's disease (CD) – chronic inflammatory diseases (CID) that often affect women of child bearing age. Adequate disease control is crucial to ensure optimal infant and maternal health and to reduce adverse pregnancy outcomes. Yet, many women with CID face inadequate disease control before pregnancy and disease flare during and after pregnancy.[2] These women have limited options when considering whether to continue treatment during pregnancy and lactation due to the potential associated health risks for fetuses and infants. They often face uncertainty regarding the use of biologics during pregnancy and breastfeeding.[3]

Data from the CRIB study offer important, new information for women with CID and their doctors. Results from the CRADLE study (NCT02154425) are also relevant for these patients. Presented this year at EULAR 2017, the study evaluated CIMZIA concentrations in human mature breast milk and found minimal to no transfer of CIMZIA to breast milk.[4]

"Tumor necrosis factor inhibitors (anti-TNFs) represent one of the most significant advances in the treatment of inflammatory diseases like rheumatoid arthritis, psoriatic arthritis, and axial spondyloarthritis/ankylosing spondylitis, but research suggests that most of these drugs cross the placenta, so they are usually discontinued during pregnancy," said Xavier Mariette, MD, PhD, Head of Rheumatology, Bicetre Hospital, Paris-Sud University, and lead author of the study.

“The CRIB study is the only clinical research that demonstrates how an effective anti-TNF, CIMZIA, shows minimal to no placental transfer from mother to infant. This is very encouraging news for female patients who have an active inflammatory disease.”

“By partnering with expert researchers, UCB has uncovered and responded to the largely unrecognized needs of women of child bearing age who have active inflammatory diseases. In response to this need, we conducted the CRIB and CRADLE studies which have shown that CIMZIA, the only Fc-free, PEGylated anti-TNF, has minimal to no transfer through the placental barrier, and minimal to no transfer through lactation,” said Emmanuel Caeymaex, Head of Immunology and Executive Vice President at UCB, Immunology Patient Value Unit, UCB.

CRIB (NCT02019602) was a pharmacokinetic study with a safety evaluation designed to measure the potential level of placental transfer of CIMZIA from pregnant women to their infants. Sixteen women (≥ 30 weeks gestation) who were already receiving CIMZIA for approved indications (RA [N=11], CD [N=3], PsA [N=1] and axSpA/AS [N=1]), were followed in the study.[1] To determine CIMZIA plasma levels, blood samples were collected from each woman, the umbilical cords, and their infants at delivery and again from infants at weeks four and eight post-delivery. The study evaluated CIMZIA concentration in the blood using a sensitive, CIMZIA-specific electrochemiluminescence immunoassay with a lower level of quantification (LLOQ) of 0.032ug/mL, which is 10 times more sensitive than prior CIMZIA assays.[1]

The study found that CIMZIA levels were below LLOQ in 13 out of 14 infant blood samples at birth, and in all samples at weeks four and eight. One infant had a minimal CZP level of 0.042ug/ML (infant/mother ratio of 0.009). No anti-CIMZIA antibodies were detected in mothers, umbilical cords, or infants, and the infants of CIMZIA-exposed mothers had a safety profile consistent with that of unexposed similar-age infants. These data indicate no to minimal placental transfer of CIMZIA from mothers to infants, suggesting lack of *in utero* fetal exposure during the second and third trimesters.[1]

In CRIB, adverse events experienced by the infants did not show any patterns or clusters of events suggesting a specific safety signal in children. Safety data in the mothers were in line with the known safety profile of CZP and pregnancy profile of these underlying diseases.

The objective of CRADLE (NCT02154425), a pharmacokinetic study with a safety evaluation, was to determine the concentration of CIMZIA in human breast milk and to calculate the average daily infant dose (ADID), an estimation of the dose of maternal CIMZIA ingested by the infant every day over the dosing interval. A post-hoc analysis also calculated the relative infant dose (RID) of CIMZIA in breast milk to provide relative context of CIMZIA data to literature available for other drugs documented during breast feeding.

In CRADLE, adverse events in the infants of mothers exposed to CIMZIA were consistent with those occurring in unexposed infants of similar age. Adverse events in mothers exposed to CIMZIA were consistent with the known safety profile of CIMZIA.[1]

In the US, CIMZIA is not indicated for axial spondyloarthritis.

In the EU, Cimzia is not indicated in Crohn's disease. CIMZIA is not recommended during pregnancy. A decision on whether to continue/discontinue breastfeeding or to continue/discontinue therapy with CIMZIA should be made taking into account the benefit of breastfeeding to the child and the benefit of CIMZIA therapy to the woman.

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.

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 May 2017. http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

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's 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

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