UCB-sponsored data on Cimzia® (certolizumab pegol) to be Highlighted at 2013 American College of Rheumatology Annual Scientific Meeting

ATLANTA – October 25, 2013 – UCB, a global biopharmaceutical company focusing on CNS and immunology treatment and research, is sponsoring multiple data presentations on Cimzia® (certolizumab pegol) for the treatment of moderate to severe rheumatoid arthritis and active psoriatic arthritis (PsA) in adults, in addition to other oral and poster presentations on investigational data. The data will be presented at the American College of Rheumatology’s (ACR) 2013 Annual Scientific Meeting in San Diego, CA, October 25-30.

“UCB strives to remain at the forefront of rheumatology research, and the multiple data sets being presented at the 2013 ACR meeting highlight our ongoing medical research aimed at helping to address the needs of patients living with a broad range of rheumatic diseases,” said Professor Dr. Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President, UCB. “Additionally, we are pleased to present new data on Cimzia for the treatment of adults with active PsA and other investigational uses.”

In the U.S., Cimzia is approved for the treatment of adults with moderately to severely active rheumatoid arthritis. In addition, it is approved 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. The FDA also recently approved Cimzia for the treatment of adults with active PsA and for adults with active AS.¹

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. Additional important safety information is included at the end of this press release.

Following is a guide to UCB-sponsored data presentations being held from Friday, October 25-Thursday, October 30, 2013.

**Cimzia for Rheumatoid Arthritis**

**Prediction Of Week 52 Treatment Response Based On A Week 12 Assessment In Rheumatoid Arthritis Patients Receiving Certolizumab Pegol: Comparison Of A Patient-Reported Instrument Versus Physician-Based Disease Activity Assessment (Trial: PREDICT)**

- Date and Time: Sunday, October 27, 9:00 AM – 4:00 PM
- Location: Hall B2-C-D
• Long-Term Safety and Efficacy Of Certolizumab Pegol In Combination With Methotrexate In The Treatment Of Rheumatoid Arthritis: 5-Year Results From a 24-Week Randomized Controlled Trial and Open-Label Extension Study (Trial: RAPID 2)
  o Date and Time: Monday, October 28, 9:00 AM – 4:00 PM
  o Location: Hall B2-C-D

• Magnetic Resonance Imaging-Assessment Of Early Response To Certolizumab Pegol In Rheumatoid Arthritis: A Randomized, Double-Blind, Placebo-Controlled Phase IIIb Study Applying Magnetic Resonance Imaging At Week 0, 1, 2, 4, 8 and 16 (Trial: MARVELOUS)
  o Date and Time: Tuesday, October 29, 9:00 AM – 4:00 PM
  o Location: Hall B2-C-D

• Long-Term Safety and Efficacy Of Certolizumab Pegol In Combination With Methotrexate In The Treatment Of Rheumatoid Arthritis: 5-Year Results From a 52-Week Randomized Controlled Trial and Open-Label Extension Study (Trial: RAPID 1 including mTSS data)
  o Date and Time: Tuesday, October 29, 9:00 AM – 4:00 PM
  o Location: Hall B2-C-D

• Comprehensive Disease Remission Achieved By Certolizumab Pegol Treatment, and Factors Associated With Certolizumab Pegol Comprehensive Disease Remission, In Rheumatoid Arthritis Patients With Predominantly High Disease Activity (Trial: J-RAPID and HIKARI)
  o Date and Time: Tuesday, October 29, 9:00 AM – 4:00 PM
  o Location: Hall B2-C-D

• Post–Hoc Analysis Showing Better Clinical Response With The Loading Dose Of Certolizumab Pegol In Japanese Patients With Active Rheumatoid Arthritis (Trial: J-RAPID and HIKARI)
  o Date and Time: Tuesday, October 29, 9:00 AM – 4:00 PM
  o Location: Hall B2-C-D

**Cimzia for Psoriatic Arthritis**

• Effect Of Certolizumab Pegol Over 48 Weeks On Signs and Symptoms In Patients With Psoriatic Arthritis With and Without Prior Tumor Necrosis Factor Inhibitor Exposure
  o Date and Time: Sunday, October 27, 9:00 AM – 4:00 PM
  o Location: Hall B2-C-D

• Reduction Of Disease Burden On Workplace and Household Productivity In Psoriatic Arthritis Over 48 Weeks Of Treatment With Certolizumab Pegol
Investigational studies of certolizumab pegol for Axial Spondyloarthritis

- Oral Presentation: Effect Of Certolizumab Pegol Over 48 Weeks In Patients With Axial Spondyloarthritis, Including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis
  - Date and Time: Monday, October 28, 4:45 PM
  - Location: Room 29D

Reduction Of Disease Burden On Workplace and Household Productivity In Axial Spondyloarthritis, Including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis, Over 48 Weeks Of Treatment With Certolizumab Pegol

- Date and Time: Monday, October 28, 9:00 AM – 4:00 PM
- Location: Hall B2-C-D

Pregnancy Data

- Retrospective Analysis Of Certolizumab Pegol Use During Pregnancy: Update Of Impact On Birth Outcomes
  - Date and Time: Sunday, October 27, 9:00 AM – 4:00 PM
  - Location: Hall B2-C-D

- Pregnancy complications in lupus: Retrospective Observational Analysis from a US Health Claims Database
  - Date and Time: Tuesday, October 29, 9:00 AM – 4:00 PM
  - Location: Hall B2-C-D

- Patient and Physician Perspectives on Family Planning and Pregnancy Issues in Systemic Inflammatory Diseases: Mind the Gap!
  - Date and Time: Tuesday, October 29, 9:00 AM – 4:00 PM
  - Location: Hall B2-C-D

About Rheumatoid Arthritis

RA affects more than 1.5 million Americans, and it is estimated that 5 million people suffer from RA globally. Prevalence is not split evenly between genders, since women are two to three times more likely to be affected than men. Although RA can affect people of all ages, the onset of the disease usually occurs between 30-50 years of age.
About Psoriatic Arthritis

Signs and symptoms of PsA include stiff, painful, swollen joints with reduced mobility, and changes to the nails. PsA affects approximately 0.24 percent of the population worldwide. Genetic and environmental factors play a role in PsA, and the disease usually occurs between the ages of 30 and 50.

About axSpA and AS

AxSpA is an inflammatory rheumatic disease that mostly affects the spine and sacroiliac joints. AxSpA can be further divided into ankylosing spondylitis (AS) and non-radiographic axSpA (nr-axSpA), depending on the presence or absence of definitive changes on x-ray in the sacroiliac joints (SIJ).

Ankylosing Spondylitis, or AS, is a chronic inflammatory rheumatic disease of the spine and is the most well-recognized subset of axSpA. The symptoms of AS can vary, but most people experience back pain and stiffness due to inflammation which can proceed to fusion of the sacroiliac joints. The condition usually begins between 15 and 35 years of age, with prevalence estimated to be .5% of the U.S. population. AS is more common in men than in women. Ankylosing spondylitis has a genetic component and is associated with the HLA-B27 gene.

IMPORTANT SAFETY INFORMATION ABOUT CIMZIA®

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 pneumocystis. 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.

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.cimzia.com

For further information

- Andrea Levin, Associate Director, PR & Communications, U.S.
  T +1 404 483 7329, andrea.Levin@ucb.com

REFERENCES


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 9000 people in approximately 40
countries, the company generated revenue of EUR 3.4 billion in 2012. UCB is listed on Euronext Brussels (symbol: UCB).

Forward Looking Statements

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.