



UCB commitment to addressing real world patient needs on display at the Annual European Congress of Rheumatology (EULAR 2016)

New data highlight breadth of UCB's pioneering portfolio with four molecules across five indications:

- An oral presentation of data from the 2 year C-EARLY™ Phase 3 study of CIMZIA®, exploring different dosing strategies
- Oral presentations from UCB's early pipeline include Phase 1b study results for bimekizumab for psoriatic arthritis and Phase 1 results for dapirolizumab pegol for systemic lupus erythematosus
- An oral presentation of Phase 3 data from the STRUCTURE study of romosozumab for osteoporosis in post-menopausal women
- Long-term data from Phase 3 trials provide analyses of four-year efficacy and safety of CIMZIA® for the treatment of psoriatic arthritis and axial spondyloarthritis

Brussels, Belgium – 8 June, 00:01 CET – UCB, a global biopharmaceutical company focusing on immunology, neurology and bone treatment and research, is proud to present pivotal, long-term data on CIMZIA® (certolizumab pegol), romosozumab, early phase molecules bimekizumab and dapirolizumab pegol, and patient-friendly injection devices in development at the Annual European Congress of Rheumatology (EULAR 2016) in London, England (8th – 11th June 2016). These data presentations offer new insights on the potential to improve patient experience and treatment outcomes across several diseases including rheumatoid arthritis (RA), psoriatic arthritis (PsA), axial spondyloarthritis (axSpA), systemic lupus erythematosus (SLE), and osteoporosis in post-menopausal women.

“The mission of UCB Immunology is to deliver value beyond expectations to our patients. We know that many people living with immunological diseases experience suboptimal response on existing therapies. This unmet need drives UCB's patient-centric approach towards scientific research and improving the patient experience,” said Emmanuel Caeymaex, Head of Immunology and Executive Vice President at UCB. “CIMZIA® data at the Annual European Congress of Rheumatology (EULAR 2016) help to build increased understanding around the product's long-term safety and efficacy profile, while our pipeline data demonstrate momentum in bringing innovative new products to patients.”

Data highlights will include four-year efficacy and safety data from both the RAPID-axSpA trial for the treatment of patients with axSpA, including ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA), and the RAPID-PsA trial for the treatment of patients with PsA. Period 2 data from the C-EARLY™ Phase 3 study will be presented, comparing different treatment strategies by continuing CIMZIA® at the standard dose or reducing the dose frequency versus withdrawal, in disease-modifying antirheumatic drug (DMARD)-naïve early RA patients who achieved sustained low disease activity after one year of treatment with certolizumab pegol combined

with optimized methotrexate.

Data being presented from UCB's pipeline include Phase 3 results from the STRUCTURE study of romosozumab for osteoporosis in post-menopausal women, Phase 1b results in PsA for bimekizumab (UCB4940), an investigational monoclonal antibody specifically designed to potently and selectively inhibit the biological function of both IL-17A and IL-17F cytokines, and Phase 1 results for dapirolizumab pegol (CDP7657), an anti-CD40L pegylated Fab fragment being evaluated for systemic lupus erythematosus (SLE).

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

Presentations on CIMZIA® in Rheumatoid Arthritis

1. **[FRIOP0227]: A Randomized Double-Blind Treatment Strategy Study Evaluating Continuation or Reduced-Frequency Dosing of Certolizumab Pegol versus Withdrawal to Maintain Low Disease Activity in Early RA Patients (C-EARLY Period 2)**
Emery, P. *et al.*
 - Date/Time: Friday 10 June, 11:00
 - Session Info: Developments in the treatment of RA; Hall D (oral presentation)
2. **[THU0163]: Early Response as a Predictor of Long-Term Clinical Response in DMARD-Naïve Patients with Severe, Active and Progressive RA Treated with Certolizumab Pegol plus Optimized MTX versus Optimized MTX Alone**
Mariette, X. *et al.*
 - Date/Time: Thursday 9 June, 11:45–13:30
 - Session Info: Rheumatoid arthritis - anti-TNF therapy; Poster area (poster presentation)
3. **[THU0128]: Maintenance of Improvements in Workplace and Household Productivity and Physical Function at 2 Years in Early RA Patients with Severe Progressive Disease Who Achieved Sustained Low Disease Activity following 1 Year of Initial Therapy, with Two Dosing Frequencies of Certolizumab Pegol**
Bingham, C. *et al.*
 - Date/Time: Thursday 9 June, 11:45 – 13:30
 - Session Info: Rheumatoid arthritis - anti-TNF therapy; Poster area (poster presentation)
4. **[THU0157]: Clinical Outcomes at Week 104 and Analysis of Associated Baseline Factors after an Initial 1 Year of Certolizumab Pegol and MTX Treatment in MTX-Naïve Patients with Early RA: Results from the Second Year of the C-OPERA Study**
Atsumi, T. *et al.*
 - Date/Time: Thursday 9 June, 11:45 – 13:30
 - Session Info: Rheumatoid arthritis - anti-TNF therapy; Poster area (poster presentation)
5. **[THU0151]: Multicenter, Open-Label Study to Evaluate the Predictability of Disease Control at Week 52 Based on Early Response to Certolizumab Pegol (in Combination**

with Methotrexate) in Italian Patients with Moderate to Severe Rheumatoid Arthritis: The CZP-SPEED Study

Sarzi-Puttini, P. *et al.*

- Date/Time: Thursday 9 June, 11:45 – 13:30
- Session Info: Rheumatoid arthritis - anti-TNF therapy; Poster area (poster presentation)

Presentations on CIMZIA® Devices

6. [SAT0631-HPR]: Chronic Disease and Self-Injection: An Ethnographic Investigation into the Patient Experience during Treatment

Schiff, M.H. *et al.*

- Date/Time: Saturday 11 June, 10:15 – 12:00
- Session Info: Health Professionals in Rheumatology; Poster area (poster presentation)

7. [THU0639-HPR]: A New Electromechanical Platform for Subcutaneous Drug Delivery: Results from an EU Usability Study

Domanska, B. *et al.*

- Date/Time: Thursday 9 June, 11:45 – 13:30
- Session Info: Health Professionals in Rheumatology; Poster area (poster presentation)

8. [AB0300]: Comparative Usability Study for a Certolizumab Pegol Auto-Injection Device in Patients with Rheumatoid Arthritis

Domanska, B. *et al.*

- Session Info: Rheumatoid arthritis – anti-TNF therapy; Publication only

9. [AB0301]: Comparison of the Bioavailability of a Single Dose of Certolizumab Pegol Injected Either by a Pre-Filled Syringe or by an Auto-Injection Device

Astruc, B. *et al.*

- Session Info: Rheumatoid arthritis – anti-TNF therapy; Publication only

Presentations on CIMZIA® in Axial Spondyloarthritis, including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis

10. [SAT0375]: Certolizumab Pegol for the Treatment of Axial Spondyloarthritis: 4-Year Outcomes from the RAPID-axSpA Trial

van der Heijde, D. *et al.*

- Date/Time: Saturday 11 June, 10:20
- Session Info: Optimising treatment of axial SpA; Poster area (poster presentation and poster tour)

11. [SAT0389]: Long-Term Improvements in Workplace and Household Productivity and Social Participation over 4 Years of Certolizumab Pegol Treatment in Patients with Axial Spondyloarthritis, including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis

van der Heijde, D. *et al.*

- Date/Time: Saturday 11 June, 10:15 –12:00
- Session Info: Spondyloarthritis - treatment; Poster area (poster presentation)

12. [THU0380]: A Single Determination of C-Reactive Protein Does Not Suffice to Declare a Patient with a Diagnosis of Axial SpA 'CRP-Negative'

Landewé, R. *et al.*

- Date/Time: Thursday 9 June, 11:50
- Session Info: Axial SpA: Clinical aspects; Poster area (poster presentation and poster tour)

Presentations on CIMZIA® in Psoriatic Arthritis

13. [FRI0471]: Certolizumab Pegol for the Treatment of Psoriatic Arthritis: 4-Year Outcomes from the RAPID-PsA Trial

Mease, P.J. *et al.*

- Date/Time: Friday 10 June, 11:45 –13:30
- Session Info: Psoriatic arthritis; Poster area (poster presentation)

14. [FRI0472]: Improvements in Joint Outcomes of Psoriatic Arthritis over 4 Years of Treatment with Certolizumab Pegol in Patients with and without Prior Anti-TNF Exposure

Mease, P.J. *et al.*

- Date/Time: Friday 10 June, 11:45 –13:30
- Session Info: Psoriatic arthritis; Poster area (poster presentation)

Presentations on CIMZIA® Across Indications

15. [THU0620]: Gender, Disease Activity, Anxiety and Depression Levels Are Related to the Levels of Fears of Patients with Rheumatoid Arthritis or Axial Spondyloarthritis: A Cross-Sectional Study of 672 Patients

Gossec, L. *et al.*

- Date/Time: Thursday June 9, 11:45 – 13:30
- Session Info: Epidemiology, health services and outcome research; Poster area (poster presentation)

16. [THU0619]: Lifestyle Beliefs of 672 Patients with Rheumatoid Arthritis or Axial Spondyloarthritis

Gossec, L. *et al.*

- Date/Time: Thursday June 9, 11:45 – 13:30
- Session Info: Epidemiology, health services and outcome research; Poster area (poster presentation)

Presentations on CIMZIA® Safety

17. [THU0136]: Use of a Global Risk Score to Identify Patients with Rheumatoid Arthritis at Risk of Serious Infectious Events During Certolizumab Pegol Treatment

Curtis, J.R. *et al.*

- Date/Time: Thursday 9 June, 11:45 – 13:30
- Session Info: Rheumatoid arthritis – anti-TNF therapy; Poster area (poster presentation)

Presentation on Bimekizumab in Psoriatic Arthritis

18. [THUOP0108]: Bimekizumab, a Monoclonal Antibody that Inhibits Both IL-17A and IL-17F, Produces a Profound Response in Both Skin and Joints: Results of an Early-Phase, Proof-of-Concept Study in Psoriatic Arthritis

Glatt, S. *et al.*

- Date/Time: Friday 10 June, 10:20
- Session Info: Expanding therapeutic options in spondyloarthritis; Hall B (oral presentation)

Presentation on Dapirolizumab Pegol

19. [THUOP0040]: Peripheral Blood Transcriptional Changes Elicited by Treatment of Systemic Lupus Erythematosus (SLE) Patients with Dapirolizumab Pegol (a Pegylated Anti-CD40L Fab')

Ranger, A. *et al.*

- Date/Time: Thursday 9 June, 10:30
- Session Info: Advances in SLE Therapeutics; Hall D (oral presentation)

Presentation on Romosozumab

20. [THUOP0100]: 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 the Phase 3 Open-label STRUCTURE Study

Langdahl, B. *et al.*

- Date/Time: Thursday 9 June, 10:20
- Session Info: Clinical Osteoporosis: new insights; Capital Suite 02 (oral presentation)

About Romosozumab

Romosozumab is an investigational bone-forming monoclonal antibody and is not approved by any regulatory authority for the treatment of osteoporosis. It is designed to work by inhibiting the protein sclerostin, and has a dual effect on bone, both increasing bone formation and decreasing bone resorption. 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. Amgen and UCB are co-developing romosozumab.

About Bimekizumab

Bimekizumab is an investigational monoclonal antibody specifically designed to potently and selectively inhibit the biological function of both IL-17A and IL-17F, two key proinflammatory cytokines. IL-17A and IL-17F are involved in chronic inflammatory processes that drive many severe skin and joint diseases. It is planned that dose-ranging studies for bimekizumab will start this year. Bimekizumab is not approved by any regulatory authority worldwide. . Amgen and UCB are co-developing romosozumab.

About Dapirolizumab Pegol

Dapirolizumab pegol (CDP7657) is an anti-CD40L pegylated Fab' being developed in systemic lupus erythematosus (SLE) jointly with Biogen, and has completed a clinical Phase 1b study at the end of 2014. The compound is scheduled to progress to Phase 2 in 2016 and is not approved by any regulatory authority worldwide.

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.

Important Safety Information about CIMZIA in the EU/EEA¹

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), asthenia, leukopenia (including lymphopenia, neutropenia), 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, pancytopenia, hypercoagulation (including thrombophlebitis, pulmonary embolism), cerebrovascular accident, vasculitis, hepatitis/hepatopathy (includes cirrhosis), and renal impairment/nephropathy (includes nephritis). In RA controlled clinical trials, 4.4% of patients discontinued taking CIMZIA due to adverse events vs. 2.7% for placebo.

CIMZIA is contraindicated in patients with hypersensitivity to the active substance or any of the excipients, active tuberculosis or other severe infections such as sepsis or opportunistic infections 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 17th December 2015.

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

References

1. CIMZIA® EU Summary of Product Characteristics. Accessed 1st May 2016 from http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

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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

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.