New UCB data demonstrates scientific innovation for immunology patients with high unmet needs at the Annual European Congress of Rheumatology (EULAR) 2017

Key presentations of data for CIMZIA® (certolizumab pegol) and from UCB's immunology pipeline include:

- Oral presentation from the CRIB study demonstrates minimal to no placental transfer of CIMZIA® during pregnancy; poster from CRADLE study finds minimal to no transfer in breast milk
- Oral presentation of the first and only four-year radiographic and MRI imaging findings on CIMZIA® efficacy for axial spondyloarthritis, including ankylosing spondylitis and non-radiographic axial spondyloarthritis
- Poster presentation of four-year data on control of psoriatic arthritis and its extra-articular manifestations in CIMZIA® patients with and without prior anti-TNF exposure
- Oral presentation on romosozumab in osteoporosis
- Poster presentations on preclinical data supporting the contribution of IL-17F to inflammation as well as the effect of dual IL-17A and IL-17F neutralization with bimekizumab on joint and skin inflammation and bone formation
- Poster presentation on the selective PI3Kδ inhibitor seletalisib for autoimmune disease

Brussels, Belgium – 14 June, 00:01 CET – UCB, a global biopharmaceutical company focusing on immunology, neurology and bone treatment and research, is presenting data on CIMZIA® (certolizumab pegol) and key pipeline molecules including bimekizumab, romosozumab, and seletalisib at the Annual European Congress of Rheumatology (EULAR) 2017 in Madrid, Spain (14 –17 June 2017).

Data highlights include an oral presentation on the results from CRIB, a prospective pharmacokinetic study showing minimal to no placental transfer from mother to fetus of CIMZIA during pregnancy. These groundbreaking findings, when considered in combination with those from a poster presentation on the CRADLE study showing minimal to no transfer of CIMZIA through breast milk, add to the clinical evidence for women with chronic inflammatory diseases and their treating physicians to make informed decisions regarding their treatment and care.

Presentations of long-term data in axial spondyloarthritis (axSpA) and psoriatic arthritis (PsA) will demonstrate UCB's commitment to bringing valuable solutions to these patients, including an oral presentation of the first four-year radiographic and MRI imaging data on CIMZIA efficacy across the full spectrum of the axSpA patient population. Long-term control of disease, through suppression of inflammation and prevention or slowing of new bone formation, is a major goal of the treatment of axSpA, including ankylosing spondylitis (AS) and non-radiographic axial spondylitis (nr-axSpA).

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Other oral and poster presentations offer preclinical data that suggest the potential of bimekizumab and seletalisib for patients with chronic immune-mediated inflammatory diseases.

“UCB engages in pioneering research that has the potential to meaningfully improve patients’ lives. Today this commitment drives us to extend the value of CIMZIA further than ever before for underserved patient populations, such as in axial spondyloarthritis and women of child bearing age with active chronic inflammatory diseases. This commitment also leads us to explore the potential of new treatments and disease management approaches for patients with unmet needs,” said Emmanuel Caeymaex, Head of Immunology and Executive Vice President at UCB. “This is what is on display at EULAR 2017 this year and we are grateful to each of the countless patients and researchers in Europe and the U.S. who have helped to bring these findings to this important rheumatology meeting.”

UCB’s 19 data presentations at EULAR demonstrate sustained and focused long-term research as well as new work on improving treatment outcomes and overall patient experience across several chronic immune-mediated inflammatory diseases, including rheumatoid arthritis (RA), PsA, and axSpA.

UCB will also sponsor two satellite symposia during EULAR. One symposium, titled “Breaking the Fragility Fracture Cycle: Can We Step Up to The Challenge?” will be held Thursday, June 15, 2017, 17:30 – 19:00, Room N11/N12, and will focus on improving management and care for patients with fragility fractures. The other symposium, titled “The Journey to Motherhood in Chronic Rheumatic Diseases” will be held Friday, June 16, 2017, 08:15 – 09 :45, Hall 7B, and will focus on the patient journey and the goals for patient care before, during, and after pregnancy in patients with chronic rheumatic diseases.

Following is a guide to the UCB data presentations and publications

Presentations on CIMZIA in Women of Child Bearing Age (WoCBA)

[OP0017]: Lack of Placental Transfer of Certolizumab Pegol During Pregnancy: Results from CRIB, A Prospective, Postmarketing, Multicenter, Pharmacokinetic Study
Mariette, X. *et al.*

- Date/Time: Wednesday 14 June, 17:25 – 17:35
- Session Info: Rheumatoid arthritis - anti-TNF therapy; Still breaking news on TNF inhibitors in rheumatoid arthritis; Hall 8 (oral presentation)

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[FRI0179]: Minimal to No Transfer of Certolizumab Pegol into Breast Milk: Results from CRADLE, A Prospective, Postmarketing, Multicenter, Pharmacokinetic Study
Clowse, M. E. B. *et al.*

- Date/Time: Friday 16 June, all day
- Session Info: Rheumatoid arthritis - anti-TNF therapy; Poster area (poster presentation)
- Poster Tour: Date/Time: Friday 16 June, 11:45 – 13:30
- Session Info: TNF inhibitors in RA = always and again (guided poster tour)

Presentations on CIMZIA in Axial Spondyloarthritis (axSpA), including Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

[OP0023]: Four-Year Imaging Outcomes in Axial Spondyloarthritis Patients Treated with Certolizumab Pegol, Including Patients with Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis
van der Heijde, D. *et al.*

- Date/Time: Wednesday 14 June, 17:05 – 17:15
- Session Info: Spondyloarthritis treatment; Progress in management of SpA; Hall 7A (oral presentation)

[OP0064]: Clefs de Dos: A Unique PARE-Led Video Program to Improve Coping Skills of People Living with Axial Spondyloarthritis
Beauvais, C. *et al.*

- Date/Time: Wednesday 14 June, 17:05 – 17:15
- Session Info: Education; Impact of rheumatic diseases; N111 / N112 (oral presentation)

Presentations/Abstract Book Publications on CIMZIA in Psoriatic Arthritis (PsA)

[FRI0508]: The Effect of Certolizumab Pegol On Extra-Articular Manifestations of Psoriatic Arthritis Over 4 Years of Treatment in Patients With and Without Prior Anti-TNF Exposure
FitzGerald, O. *et al.*

- Date/Time: Friday 16 June, all day
- Session Info: Psoriatic arthritis; Poster Session II; Poster area (poster presentation)

[AB0747]: The Effect of Certolizumab Pegol On Radiographic Progression Over 4 Years of Treatment in Patients with Psoriatic Arthritis
van der Heijde, D. *et al*.

- Publication Topic: Psoriatic arthritis
- Publication Number: AB0747 (no presentation)

[FRI0489]: Certolizumab Pegol Is Associated with Long-Term Improvements in Patient-Reported Outcomes in Psoriatic Arthritis: 4-Year Outcomes from the Rapid-PsA Study
Gladman, D. *et al.*

- Date/Time: Friday 16 June, all day
- Session Info: Psoriatic arthritis; Poster Session II; Poster area (poster presentation)

<u>Presentation on CIMZIA in Rheumatoid Arthritis (RA)</u>

[SAT0050]: Early Response to Certolizumab Pegol in Rheumatoid Arthritis Predicts Outcome: Data from a Prospective Observational Study
Saraux, A. *et al.*

- Date/Time: Saturday 17 June, all day
- Session Info: Rheumatoid arthritis - prognosis, predictors and outcome; Poster Session III; Poster area (poster presentation)

[THU0589]: Patient-Perceived Coping Was Associated with Patient-Perceived Quality of Patient-Physician Interactions in 320 Patients with Rheumatoid Arthritis
Gossec, L. *et al.*

- Date/Time: Thursday 15 June, all day
- Session Info: Education; Poster Session I; Poster area (poster presentation)

<u>Abstract Book Publications on CIMZIA Devices</u>

[AB1113]: Patient Participation Is Crucial When Introducing New Device Technologies in the Management of Chronic Arthritis: Applying The Parker Model, A Qualitative 3-Step Approach
Jørgensen, T. S. *et al.*

- Publication topic: Public health, health services research and health economics
- Publication number: AB1113 (no presentation)

[THU0588]: Are Rheumatoid Arthritis Patients Willing to Use an E-Health Interactive Self-Assessment Website? Analyses of 159 Patients from a Randomised Controlled Trial Over

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12 Months
Gossec, L. *et al.*

- Date/Time: Thursday 15 June; all day
- Session Info: Education; Poster Session I; Poster area (poster presentation)

Presentations for Multiple Disease States

[THU0675]: Development and Psychometric Validation of a Tool to Assess the Fears of Patients with Chronic Inflammatory Rheumatic Diseases: The Fair Scale
Gossec, L. *et al.*

- Date/Time: Thursday 15 June, all day
- Session Info: Validation of outcome measures and biomarkers; Poster Session I; Poster area (poster presentation)

[FRI0193]: Effect of Valency of Anti-TNFs on Elimination Mediated by Anti-Drug Antibodies
Silva, J. *et al.*

- Date/Time: Friday 16 June, all day
- Session Info: Rheumatoid arthritis - anti-TNF therapy; Poster Session II; Poster area (poster presentation)

[AB1155]: Depression and Suicidality Are Common in Psoriatic Arthritis and Axial Spondyloarthritis, And Rates Are Comparable to Those in Psoriasis
Sheahan, A. *et al.*

- Publication topic: Epidemiology, risk factors for disease or disease progression
- Publication number: AB1155 (no presentation)

Presentations on Romosozumab

[OP0050]: The Treatment Gap After Fracture in Osteoporosis Patients in Sweden
Spångéus, A. *et al.*

- Date/Time: Wednesday 14 June, 17:35 – 17:45
- Session Info: Osteoporosis treatment gap, new options and new strategies; South Auditorium (oral presentation)

[OP0048]: Romosozumab Rapidly Reduces Clinical Vertebral Fracture Incidence: Results from the FRAME Study
Geusens, P. *et al.*

- Date/Time: Wednesday 14 June, 17:15 – 17:25

- Session Info: Osteoporosis treatment gap, new options and new strategies; South Auditorium (oral presentation)

Presentations on Bimekizumab

[THU0038]: Bimekizumab Dual Inhibition of IL-17A and IL-17F Provides Evidence of IL-17F Contribution to Chronic Inflammation in Disease-Relevant Cells
Maroof, A. *et al.*

- Date/Time: Thursday 15 June, all day
- Session Info: Cytokines and inflammatory mediators; Poster Session I; Poster area (poster presentation)

[THU0060]: T Cell-Derived IL-17A and IL-17F Drive Bone Formation from Human Periosteal Stem Cells: Implications for Enthesophyte Formation
Shah, M. *et al.*

- Date/Time: Thursday 15 June, all day
- Session Info: Cytokines and inflammatory mediators; Poster Session I; Poster area (poster presentation)

Presentations/Abstract Book Publications on Seletalisib

[THU0220]: Seletalisib, a Novel Selective PI3Kδ Inhibitor with Therapeutic Potential in Inflammation and Autoimmunity
Payne, A. *et al.*

- Date/Time: Thursday 15 June, all day
- Session Info: SLE, Sjögren's and APDS - etiology, pathogenesis and animal models; Poster area (poster presentation)
- Poster Tour: Date/Time: Thursday 15 June, 11:45 – 13:30
- Session Info: Pathomechanism in SLE, SS, APS (guided poster tour)

About Romosozumab
Romosozumab is an investigational bone-forming monoclonal antibody that is not currently 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.

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About Bimekizumab
Bimekizumab is an investigational humanized IgG1 monoclonal antibody rationally designed to potently and selectively neutralize the biological function of both IL-17A and IL-17F, two key pro-inflammatory cytokines. IL-17A and IL-17F are closely related cytokines that are co-expressed at sites of inflammation and both independently co-operate with other cytokines to mediate chronic inflammatory responses driving many severe skin and joint diseases. Dose-ranging studies for bimekizumab have also started. Bimekizumab is not approved by any regulatory authority worldwide.

About Seletalisib
Seletalisib is a new chemical entity and is a potent and highly selective phosphoinositide 3 kinase delta (PI3Kδ) inhibitor with the potential for use in the treatment of immune-inflammatory diseases. Initial clinical investigations in healthy volunteers suggest that seletalisib is well tolerated at doses that are anticipated to have therapeutic potential and is suitable for oral, once-daily administration. Seletalisib 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).

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- 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.

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.

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.

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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 7,500 people in approximately 40 countries, the company generated revenue of € 4.2 billion in 2016. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

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.