



New UCB Data Presented at the Annual European Congress of Rheumatology (EULAR 2018) Serves Key Patient Populations Including Ankylosing Spondylitis, Psoriatic Arthritis, and Women with Chronic Inflammatory Diseases

- Late-breaking oral presentation on bimekizumab shows significant potential for treating ankylosing spondylitis (AS)
- Oral presentation on CIMZIA® (certolizumab pegol) pregnancy outcomes shows no increased risk of major congenital malformations compared to the general population nor an increased risk of fetal death
- Multiple presentations reveal perceptions, challenges and practices relative to women of childbearing age with chronic inflammatory diseases and the physicians who treat them
- Four-year RAPID-PsA data confirm sustained remission and minimal disease activity in patients with psoriatic arthritis (PsA) treated with CIMZIA

Brussels, Belgium – 7 June 2018 – UCB, a global biopharmaceutical company focusing on immunology, neurology and bone treatment and research, will be presenting new data on CIMZIA® (certolizumab pegol) and key pipeline molecules bimekizumab and romosozumab at the Annual European Congress of Rheumatology (EULAR 2018), taking place in Amsterdam, June 13-16, 2018.

As a part of a late-breaking oral presentation, week 12 findings from the BE AGILE study will be presented for the first time, revealing the promising treatment effect of bimekizumab in patients living with ankylosing spondylitis (AS) and suggesting the potential breakthrough value of neutralizing IL-17F in addition to IL-17A. A separate presentation of long-term findings from RAPID-PsA on CIMZIA in psoriatic arthritis (PsA) will focus on the sustained achievement of stringent clinical outcomes, with a substantial proportion of patients achieving complete remission or very low disease activity.

An additional oral presentation will offer insight into the positive effect in building bone with one year of romosozumab.

“We are proud to present impressive findings on our pipeline molecules as well as the sustained value of CIMZIA in populations with specific treatment needs, such as women of childbearing age and patients with PsA and AS. The data that will be presented this week exemplify our mission to understand the needs of underserved patient populations, and connect them with scientific advancements that can provide real and immediate impact,” said Emmanuel Caeymaex, Head of Immunology and Executive Vice President, Immunology Patient Value Unit, UCB. “We are committed to serving as partners in care by understanding and supporting patients and rheumatologists, who are engaging especially challenging treatment situations, so we can bring the broadest possible value to patients in need.”

Additional presentations include survey findings from both patients and healthcare professionals (HCP) on specific challenges involved in the treatment of chronic inflammatory diseases in women of childbearing age. Findings from the patient survey, “Fears and Misconceptions of Women with Chronic Rheumatic Disease on Their Journey to Motherhood,” suggest that many women’s decisions to delay pregnancy or interrupt their treatment may be linked to the need for greater awareness of disease management options and earlier consultation with their HCPs. Also to be presented are findings from a SERMO survey of practicing HCPs, exploring the physician perspective on the challenges specific to treating women with chronic inflammatory diseases during family planning. Results from the largest published cohort of pregnant women exposed to an anti-TNF during pregnancy that will be presented at EULAR 2018 confirm that patients treated with certolizumab pegol did not experience increased risk of major congenital malformations compared to the general population nor an increased risk of fetal death.

Real world experiences of patients living with rheumatoid arthritis (RA) are explored in a poster presentation featuring analysis of data from the ArthritisPower Registry. Data suggest that rheumatologists tended to forego treatment changes, even when disease control goals were not met, with patients usually deferring to their HCPs. Other CIMZIA data featured at EULAR 2018 include data on ava, the auto-injection e-device, and the impact of the Coach@Home patient support program.

In addition to 11 data presentations, UCB will be sponsoring two satellite symposia highlighting research and innovations in the treatment landscapes of osteoporosis and axial spondyloarthritis (axSpA). The data presented by UCB at EULAR 2018 showcase the company’s commitment to connecting scientific innovation and insights into real-world patient goals and unmet needs to make a lasting difference in the lives of patients.

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

UCB Sponsored Symposia

The Reality of Risk – How Are we Responding to Fragility Fracture in Rheumatology, S. Papapoulos, I. Bruce, I. Vlaav

- Date/Time: June 13, 2018: 18:15-19:30 CEST

Axial Spondyloarthritis in 2018: New Data, Less Compromise?, M. Rudwaleit, L. Gensler, M. Dougados, D. Poddubnyy

- Date/Time: June 15, 2018: 08:15-9:45 CEST

Presentations on UCB's Investigational Pipeline:

Dual Neutralization of IL-17A and IL-17F with Bimekizumab in Patients With Active Ankylosing Spondylitis: 12-Week Results From a Phase 2b, Randomised, Double-Blind, Placebo-Controlled, Dose-Ranging Study, D. van der Heijde, L. Gensler, A. Deodhar, X. Baraliakos, D. Poddubnyy, M. K. Farmer, D. Baeten, T. Kumke, M. Oortgiesen, M. Dougados

- Date/Time: June 13, 2018: 16:15 - 17:45 CEST

FRAME Study: The Foundation Effect of Rebuilding Bone With One Year of Romosozumab Leads to Continued Lower Fracture Risk After Transition to Denosumab, F. Cosman, D. B. Crittenden, S. Ferrari, A. Khan, N. E. Lane, K. Lippuner, T. Matsumoto, C. E. Milmont, C. Libanati, A. Grauer

- Date/Time: June 15, 2018: 15:30 - 17:00 CEST

CIMZIA® Presentations:

Certolizumab Pegol Provides Sustained Remission and Minimal Disease Activity in Patients With Psoriatic Arthritis Over 4 Years' Treatment, D. van der Heijde, A. Deodhar, O. FitzGerald, R. Fleischmann, D. Gladman, A. B. Gottlieb, L. C. Coates, B. Hoepken, L. Bauer, L. Peterson, M. Khraishi, P. J. Mease

- Date/Time: June 16, 2018: 10:30 – 12:00 CEST

Characteristics and Outcomes of Prospectively Reported Pregnancies Exposed to Certolizumab Pegol From a Safety Database, M. E. B. Clowse, A. E. Scheuerle, C. Chambers, A. Afzali, A. Kimball, J. J. Cush, M. Cooney, L. Shaughnessy, M. Vanderkelen, F. Förger

- Date/Time: June 14, 2018: 13:30 - 15:00 CEST

Comparison of the Bioavailability of a Single Dose of Certolizumab Pegol Injected by Pre-Filled Syringe or by Electro-Mechanical Auto-Injection e-Device: a Phase 1, Open-Label, Randomized, Parallel Group, Single-Centre Bioequivalence Study, R. Oliver, B. VanLunen, I. Mountian, E. Brown, D. Tatla

- Date/Time: June 16, 2018: 10:30 – 12:00 CEST

UCB-sponsored Data on Women of Childbearing Age:

Fears and Misconceptions of Women with Chronic Rheumatic Diseases on Their Journey to Motherhood, A. Tincani, P. Taylor, R. Fischer-Betz, C. Ecoffet, E. Chakravarty

- Date/Time: June 15, 2018: 11:45 - 13:30 CEST

Anti-TNF Treatments for Women With Chronic Inflammatory Diseases: Comparing Attitudes and Perceptions of Physicians in Europe and the US, A. Tincani, P. Taylor, R. Fischer-Betz, C. Ecoffet, E. Chakravarty

- Date/Time: June 15, 2018: 11:45 - 13:30 CEST

Pregnancy Outcomes and Disease Activity in Women with Axial Spondyloarthritis: A Systematic Literature Review A. Moltó, L. Gensler, M. Clowse, H. Marzo-Ortega, A. Artignan, D. Goff-Leggett, S. Leonard, H. Resemann, E. Thurtle, N. de Peyrecave, C. Ecoffet, F. Förger

- Date/Time: June 14, 2018: 11:45 - 13:30 CEST

UCB-sponsored Rheumatology Data:

Baseline Characteristics and Patient Satisfaction Data from Coach@Home: The German Support Program for Patients with Rheumatic Diseases Treated with Certolizumab Pegol, N. Böhme, A.-D. Holst, F. Dybowski, C. Volberg, H.-G. Pott, U. Lendl

- Date/Time: ePoster only

Barriers to Rheumatoid Arthritis Treatment Optimisation: Real-World Data from the ArthritisPower Registry, J. L. Stark, M. Yassine, W. B. Nowell, K. Gavigan, S. Ginsberg, M. S. Serna, J. R. Curtis

- Date/Time: June 14, 2018: 11:45 - 13:30 CEST

Do TNF Inhibitors Impact the Comorbidities and Extra-Articular Manifestations, and Thereby Alter the Natural History of Ankylosing Spondylitis? A. Deodhar, K. L. Winthrop, R. L. Bohn, B. K. Chan, R. Y. Suruki, J. L. Stark, H. Yun, S. A. R. Siegel, L. Chen, M. Yassine, J. R. Curtis

- Date/Time: June 16, 2018: 10:30 CEST

About Bimekizumab

Bimekizumab is a novel humanized monoclonal IgG1 antibody that potently and selectively neutralizes both IL-17A and IL-17F, two key cytokines driving inflammatory processes. IL-17A and IL-17F have overlapping pro-inflammatory functions and independently cooperate with other inflammatory mediators to drive chronic inflammation and damage across multiple tissues.

Previous early Phase clinical studies in psoriasis and psoriatic arthritis have suggested that neutralizing IL-17F in addition to IL-17A with bimekizumab may provide a new targeted approach for the treatment of immune-mediated inflammatory diseases. Preclinical results in disease-relevant cells have shown that dual neutralization of both IL-17A and IL-17F reduces skin and joint inflammation, as well as pathological bone formation to an extent greater than inhibition of IL-17A or IL-17F alone.^{i,ii,iii}

UCB is studying bimekizumab in psoriasis, psoriatic arthritis and ankylosing spondylitis. Bimekizumab is not approved by any regulatory authority worldwide.

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 activity of sclerostin, which enables romosozumab to increase bone formation and reduce bone resorption simultaneously. 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 11,000 postmenopausal women with osteoporosis. Amgen and UCB are co-developing romosozumab.

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), 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 haematologic 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 January 2018.

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

CIMZIA[®] is a registered trademark of the UCB Group of Companies.

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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 in immunology or neurology. With more than 7,500 people in approximately 40 countries, the company generated revenue of € 4.5 billion in 2017. 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.

ⁱ Glatt S, Baeten D, Baker T, et al. Dual IL-17A and IL-17F neutralisation by bimekizumab in psoriatic arthritis: evidence from preclinical experiments and a randomized placebo-controlled clinical trial that IL-17F contributes to human chronic tissue inflammation. *Ann Rheum Dis*. In Press.

ⁱⁱ Shah M, Maroof A, Al-Hosni R, Gikas P, Gozzard N, Shaw S, Roberts S. Bimekizumab Blocks T Cell-Mediated Osteogenic Differentiation of Periosteal Stem Cells: Coupling Pathological Bone Formation to IL-17A and IL-17F Signaling [abstract]. *Arthritis Rheumatol*. 2017; 69 (suppl 10).

ⁱⁱⁱ Maroof A, Okoye R, Smallie T, et al. Bimekizumab dual inhibition of IL-17A and IL-17F provides evidence of IL-17F contribution to chronic inflammation in disease-relevant cells. *Ann Rheum Dis*. 2017;66(suppl.2):213-213.