



Data Presented at EADV 2018 Further Demonstrate the Value of CIMZIA® (certolizumab pegol) and Bimekizumab, as UCB Commitment to Psoriasis and Immuno-Dermatology Grows

- Pooled data from three Phase 3 psoriasis studies focus on CIMZIA® (certolizumab pegol) dose durability of treatment response through 48 weeks
- Two sub-analyses from the Phase 3 CIMPACT study show the potential value of CIMZIA for psoriasis patients who were PASI 75 non-responders and for those who responded to prior treatment
- New Phase 2b bimekizumab findings show the positive effect of dual neutralization of IL-17A and IL-17F on disease-specific quality of life and support the association of high levels of skin clearance with excellent scores in quality of life improvements in psoriasis
- Oral e-poster presentation reveals differing perceptions and confidence levels about treating women with chronic inflammatory disease among U.S. and European dermatologists and other specialists

Brussels, Belgium – 13th September 2018 – UCB, a global biopharmaceutical company, will be presenting new findings on CIMZIA® (certolizumab pegol), the only Fc-free, PEGylated anti-TNF, and one of its key pipeline molecules, bimekizumab, for the treatment of moderate-to-severe chronic plaque psoriasis (PSO), along with findings from an international survey on physicians' perceptions about treating women with chronic inflammatory disease, such as psoriatic arthritis (PsA) and PSO. Presentations will be made this week at the 27th European Academy of Dermatology and Venereology (EADV) Congress, taking place in Paris, September 12-16, 2018.

Findings presented this week at EADV suggest efficacy and safety, response durability and dose flexibility of CIMZIA in diverse PSO patient populations. Two separate sub-analyses from the Phase 3 study, CIMPACT, studied disease activity in patients following transition to CIMZIA therapy after being treated with etanercept (Enbrel®). Findings suggest the potential value of CIMZIA to induce and maintain beneficial skin response, both in patients who were primary non-responders as well as those who responded to etanercept. Other findings based on pooled data from the ongoing Phase 3 PSO studies, CIMPASI-1, CIMPASI-2 and CIMPACT, confirm durable efficacy for CIMZIA across indicated doses.

New findings from the Phase 2b BE ABLE study on bimekizumab focus on disease-specific health-related quality of life (HRQoL) and associated levels of skin clearance in PSO. Bimekizumab potently and selectively neutralizes both IL-17A and IL-17F, two key cytokines driving inflammatory processes.

"This year has proven to be the most ambitious for UCB in immuno-dermatology, and our commitment to this community is clearly seen at this year's EADV conference. Growing evidence from all three ongoing Phase 3 CIMZIA trials suggests potential value for a range of underserved patient populations living with psoriasis. Following approval earlier this year by both the European Medicines Agency (EMA) and the U.S. Food and

Drug Administration (FDA), we are working to reach as many of these patients as possible,” said Emmanuel Caeymaex, Head of Immunology and Executive Vice President at UCB. “Also evident at EADV is our commitment to future solutions, including new measures of the value of dual neutralization of both IL-17A and IL-17F provided by our investigational molecule bimekizumab, and research that advances our partnership with physicians working to better address the special needs of women of childbearing age with inflammatory diseases.”

An additional oral presentation will include full survey findings from an international study of physicians, including dermatologists, obstetricians and gynecologists, reflecting varying levels of confidence about treating chronic inflammatory disease, such as PsA and PSO, among women of childbearing age with tumor necrosis factor antagonists (anti-TNFs), and suggesting the value of additional information and education.

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

CIMZIA®

(P1856) Efficacy of Certolizumab Pegol in Psoriasis Patients Failing to Respond to Etanercept: Results from an Ongoing, Phase 3, Randomised Controlled Study, M. Augustin, J. Węglowska, M. Lebwohl, V. Piguët, H. Sofen, A. Blauvelt, L. Peterson, C. Arendt, R. Rolleri

- Date/Time: September 12, 2018, 18:00 CET
- E-Poster Hall

(P1880) Maintenance of Clinical Response in Patients with Chronic Plaque Psoriasis Switching from Etanercept to Certolizumab Pegol in a Phase 3, Randomised, Controlled Study, M. Augustin, J. Węglowska, M. Lebwohl, C. Paul, V. Piguët, H. Sofen, A. Blauvelt, L. Peterson, C. Arendt, R. Rolleri

- Date/Time: September 12, 2018, 18:00 CET
- E-Poster Hall

(P1882) Durability of Response in Patients with Chronic Plaque Psoriasis Treated with Certolizumab Pegol over 48 Weeks: Pooled Results from Ongoing Phase 3, Multicentre, Randomised, Placebo-Controlled Studies, M. Augustin, J. Węglowska, M. Lebwohl, C. Paul, V. Piguët, H. Sofen, A. Blauvelt, L. Peterson, R. Rolleri, K. Reich, D. Thaçi, C. Leonardi, Y. Poulin, C. Arendt, A. B. Gottlieb

- Date/Time: September 12, 2018, 18:00 CET
- E-Poster Hall

Bimekizumab

(P1978) Dual neutralisation of IL-17A and IL-17F with bimekizumab improves quality of life in patients with moderate-to-severe plaque psoriasis: results from a Phase 2b study and correlation with clinical response, K. A. Papp, J. F. Merola, A. B. Gottlieb, C. E. M. Griffiths, K. K. Harris, N. Cross, L. Peterson, C. Cioffi, A. Blauvelt

- Date/Time: September 12, 2018, 18:00 CET
- E-Poster Hall

Treatment of Women of Childbearing Age with Chronic Inflammatory Disease

(OP01.06) Anti-TNF Treatments for Women with Chronic Inflammatory Diseases: Comparing Attitudes and Perceptions of Physicians in Europe and the US, C. Ryan, J. Murase, C. Ecoffet, A. Van Voorhees

- Date/Time: September 13, 2018, 10:35-10:45 CET
- Room 311-312

UCB Supported Symposia

Navigating the Road to Psoriasis Control: Considering the Woman in the Patient, PeerVoice

- Date/Time: September 15, 2018, 17:00-18:30 CET

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 CIMZIA in Psoriasis

CIMZIA is the first Fc-free, PEGylated anti-TNF treatment option for psoriasis. CIMZIA provides psoriasis patients and their dermatologists with leading efficacy and two different doses to maximize disease control, achieve clear skin and face the serious quality-of-life challenges that often accompany plaque psoriasis.^{iv} Additionally, a recent European Medicines Agency (EMA) label update for CIMZIA in pregnancy and breastfeeding, makes CIMZIA the first anti-TNF for potential use in women during both pregnancy and lactation in its approved indications.^{v,vi,vii} With 10 years of clinical experience, CIMZIA has an established safety and efficacy profile and has treated more than 100,000 patients living with rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis, and Crohn's disease.^{viii}

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.

CIMZIA is also indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

About CIMZIA® in Fertility, Pregnancy and Lactation in the EU/EEA

Women of childbearing potential

The use of adequate contraception should be considered for women of childbearing potential. For women planning pregnancy, continued contraception may be considered for 5 months after the last CIMZIA dose due to its elimination rate, but the need for treatment of the woman should also be taken into account (see below).

Pregnancy

Data from more than 500 prospectively collected pregnancies exposed to CIMZIA with known pregnancy outcomes, including more than 400 pregnancies exposed during the first trimester, does not indicate a malformative effect of CIMZIA. However, the available clinical experience is too limited to, with a reasonable certainty, conclude that there is no increased risk associated with CIMZIA administration during pregnancy.

Animal studies using a rodent anti-rat TNF α did not reveal evidence of impaired fertility or harm to the foetus. However, these are insufficient with respect to human reproductive toxicity. Due to its inhibition of TNF α , CIMZIA administered during pregnancy could affect normal immune response in the newborn.

CIMZIA should only be used during pregnancy if clinically needed. Non-clinical studies suggest low or negligible level of placental transfer of a homologue Fab-fragment of certolizumab pegol (no Fc region).

In a clinical study 16 women were treated with certolizumab pegol (200 mg every 2 weeks or 400 mg every 4 weeks) during pregnancy. Certolizumab pegol plasma concentrations measured in 14 infants at birth were Below the Limit of Quantification (BLQ) in 13 samples; one was 0.042 µg/ml with an infant/mother plasma ratio at birth of 0.09%. At Week 4 and Week 8, all infant concentrations were BLQ. The clinical significance of low levels certolizumab pegol for infants is unknown. It is recommended to wait a minimum of 5 months following the mother's last CIMZIA administration during pregnancy before administration of live or live-attenuated vaccines (e.g. BCG vaccine), unless the benefit of the vaccination clearly outweighs the theoretical risk of administration of live or live-attenuated vaccines to the infants.

Breastfeeding

In a clinical study in 17 lactating women treated with CIMZIA, minimal transfer of certolizumab pegol from plasma to breast milk was observed. The percentage of the maternal certolizumab pegol dose reaching an infant during a 24 hour period was estimated to 0.04% to 0.30%. In addition, since certolizumab pegol is a protein that is degraded in the gastrointestinal tract after oral administration, the absolute bioavailability is expected to be very low in a breastfed infant. Consequently, CIMZIA can be used during breastfeeding.

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 herpeszoster, 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 (including miliary, disseminated and extrapulmonary), 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 and moderate to severe heart failure.

Serious infections including sepsis, tuberculosis and opportunistic infections (e.g. histoplasmosis, nocardia, candidiasis) 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® until the infection is controlled. 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, including multiple sclerosis; 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 cytopenia, have been 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) and in 409 patients with psoriatic arthritis (PsA) for up to 4 years. The safety profile for axSpA and PsA patients treated with Cimzia® was consistent with the safety profile in RA and previous experience with Cimzia®.

Cimzia® was studied in 1112 patients with psoriasis in controlled and open-label studies for up to 18 months. The safety profile of Cimzia® 400 mg every 2 weeks and Cimzia® 200 mg every 2 weeks were generally similar.

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information. European SmPC date of revision June 2018. <http://www.medicines.org.uk/emc/medicine/22323>
<http://www.medicines.org.uk/emc/medicine/32367>

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

For further information, UCB:

Corporate Communications

France Nivelles,
Global Communications, UCB

T +32.2.559.9178,
france.nivelles@ucb.com

Laurent Schots,
Media Relations, UCB
T +32.2.559.92.64,
laurent.schots@ucb.com

Investor Relations

Antje Witte,
Investor Relations, UCB

T +32.2.559.94.14,
antje.witte@ucb.com

Brand Communications

Andrea Levin Christopher,
Immunology Communications, UCB

T +1.404.483.7329
andrea.christopher@ucb.com

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., Griffiths M., Ionescu L. 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.* 2018; 77(4):523–32.

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 [ACR abstract 1936]. *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. [EULAR abstract THU0038] *Ann Rheum Dis.* 2017;76 (suppl.2):213-213.

^{iv} UCB Data on File.

^v CIMZIA. Summary of Product Characteristics (SmPC), 2018.

^{vi} Mariette X, Förger F, Abraham B, et al. Lack of Placental Transfer of Certolizumab Pegol During Pregnancy: Results from CRIB, a Prospective, Postmarketing, Multicenter, Pharmacokinetic Study. *Ann Rheum Dis.* 2018;77(2):228-233.

^{vii} Clowse ME, Förger F, Hawng C, et al. Minimal to no transfer of certolizumab pegol into breast milk: results from CRADLE, a prospective, postmarketing, multicentre, pharmacokinetic study. *Ann Rheum Dis.* 2017;76:1890–1896.

^{viii} UCB Data on File.