UCB News

**New UCB Research Showcases Value of CIMZIA® (certolizumab pegol) in Psoriasis and Highlights Unique Experiences and Real World Evidence for Key Patient Populations**

*CIMZIA, the only Fc-free, PEGylated anti-TNF, recently received marketing authorization from the European Commission for the treatment of adults with moderate to severe plaque psoriasis*

**Brussels, Belgium – 28 June 2018 –** UCB, a global biopharmaceutical company focusing on immunology, neurology and bone treatment and research, is sponsoring several presentations on CIMZIA® (certolizumab pegol) in psoriasis, as well as research on the impact of psoriasis on patients, especially women, and how to optimize disease management, at the 5th World Psoriasis & Psoriatic Arthritis Conference 2018, presented by the International Federation of Psoriasis Associations (IFPA) in Stockholm, June 27-30.

"We are proud to partner with the global psoriasis community at IFPA to present data that demonstrates UCB'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 psoriasis patients. We have undertaken research that not only demonstrates the clinical value and durability of CIMZIA, the first and only Fc-free, PEGylated anti-TNF treatment option for psoriasis, but also explores the significant toll that psoriasis takes on patients, particularly women, and how patient care and outcomes can be improved," said Emmanuel Caeymaex, Head of Immunology and Executive Vice President, Immunology Patient Value Unit, UCB. "With the recent European Commission marketing authorization for CIMZIA in psoriasis, UCB is making an exciting entry into immuno-dermatology. We look forward to continued partnership with the psoriasis community to bring value to patients. This is exemplified by our Phase 3 development program for bimekizumab in psoriasis, which includes head-to-head studies with Cosentyx®, Stelara®, and Humira®."

Several presentations show the efficacy, durability, and safety of certolizumab pegol in adult patients with moderate-to-severe plaque psoriasis. Pooled data from CIMPASI-1 and CIMPASI-2, pivotal Phase 3 clinical trials of certolizumab pegol in psoriasis, demonstrate that patients maintained their clinical response from week 16 through week 48.[1] Additional pooled data from these two studies also show that higher proportions of certolizumab pegol-treated patients achieved improvements in the Psoriasis Area Severity Index (PASI), as well as improved scores in important quality of life measures, versus placebo, at week 16.[2,3] Reductions in absolute PASI were further consolidated through week 48.[4]

An additional analysis of pooled data from these studies assessed the efficacy of certolizumab pegol up to 48 weeks across patient subgroups, including body weight, disease duration, and prior biologic therapy, finding clinically meaningful efficacy across these important patient populations.[5]

The results for all pooled data were observed with both maintenance dose regimens of 200 mg and 400 mg of certolizumab pegol administered every two weeks.[1-5]

Research on women with psoriasis considering pregnancy, or who conceived within the last five years, uncovers the unique needs and treatment challenges of disease management for this patient population. A survey was conducted to evaluate experiences, concerns and family planning needs, and results suggest that patients who were taking systemic therapy and considering pregnancy may

delay or fail to inform their psoriasis treatment provider of their pregnancy. The survey was funded by UCB and conducted by the National Psoriasis Foundation in the US.[6]

An evaluation of differences in the psychosocial impact of plaque psoriasis on quality of life in men and women in early adulthood found that women tended to report a greater effect of psoriasis on their day to day lives than men of a similar age, both physically in terms of pain, and psychosocially in terms of relationships and mental health.[7]

Additional presentations highlight real world evidence for improving patient care. A presentation on Coach@home, a German program that offers support and guidance to CIMZIA-treated patients with rheumatoid arthritis, axial spondyloarthritis, and psoriatic arthritis, showed a high level of satisfaction from patients who participated in the program.[8] Another presentation looks at the frequency of inadequate response to first-line biologic therapies in patients with psoriasis, and the reasons underlying this lack of response, in a real-world setting.[9]

At IFPA, UCB is also sponsoring a satellite symposium focused on unmet medical needs in psoriasis and impact on quality of life, particularly in women. The symposium, “Evidence-based medicine: Why still compromise in the treatment of psoriatic disease?” will take place Saturday, June 30th, 07:30-08:15 CEST in the Stockholm Waterfront Congress Centre Conference Hall.

**All UCB-sponsored presentations will be presented as posters and will be available throughout the duration of the meeting.**

**Certolizumab Pegol Value in Psoriasis – Efficacy, Durability and Safety**

***Poster 46:*** **Safety of Certolizumab Pegol over 48 Weeks in Chronic Plaque Psoriasis Phase 3 Trials**, A. Blauvelt, B. Strober, R. Langley, D. Burge, L. Pisenti, M. Yassine, S. Kavanagh, C. Arendt, R. Rolleri, M. Lebwohl, K. Reich

***Poster 053:*** **Durable Reduction in Absolute PASI with Certolizumab Pegol in Patients with Chronic Plaque Psoriasis**, A. B. Gottlieb, A. Blauvelt, D. Thaçi, C. Leonardi, Y. Poulin, L. Peterson, C. Arendt, M. Boehnlein, K. Gordon, K. Reich

***Poster 057:*** **Durability of Response in Certolizumab Pegol-Treated Patients over 48 Weeks in CIMPASI-1 & 2 Trials**, K. Reich, A. Blauvelt, D. Thaçi, C. Leonardi, Y. Poulin, L. Peterson, C. Arendt, A. B. Gottlieb

***Poster 59:*** **Certolizumab Pegol Is Effective for Chronic Plaque Psoriasis Across Patient Subgroups,** K. Reich, A. Blauvelt, D. Thaçi, C. Leonardi, Y. Poulin, D. Burge, L. Peterson, C. Arendt, A. B. Gottlieb

***Poster 141:*** **Certolizumab Pegol Improves Patient-Reported Outcomes in Chronic Plaque Psoriasis Over 1 Year**, D. Thaçi, A. B. Gottlieb, K. Reich, J. Bagel, L. Peterson, O. Purcaru, J. Węgłowska

**Unique Experiences and Real-World Evidence**

***Poster 88:*** **Frequency of Inadequate Response to Treatment among Psoriasis Patients on First-Line Biologics**, A. Sheahan, E. Lee, L. Pisenti, M. Yassine, R. Suruki

***Poster 138:*** **Coach@Home: The Holistic Support Program for Patients Treated with Certolizumab Pegol**, N. Böhme, A-D. Holst, F. Dybowski, C. Volberg, H-G. Pott, U. Lendl

**Optimizing Disease Management in Women**

***Poster 139:*** **A Comprehensive Survey Assessing the Family Planning Needs of Women with Psoriasis**, M. Lebwohl, A. S. Van Voorhees, M. Siegel, L. Shankle, L. Pisenti, M. Yassine

***Poster 140:*** **The Psychosocial Impact of Psoriasis: Differential Experiences of Men and Women in Early Adulthood,** C. Ryan, C. Vandeloo, D. Munro, A. Arjona

**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.[10] 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.[*11,12,13] 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. [†14]

**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.

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[*]The 400 mg dose of CIMZIA administered every two weeks was not included in CRIB and CRADLE, prospective pharmacokinetic studies that measured transfer of certolizumab pegol via the placenta during pregnancy and into breast milk during lactation, respectively.

[†] CIMZIA is not approved by EMA for the treatment of Crohn's disease.

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

**Important Safety Information about CIMZIA® in the EU/EEA**
Cimzia® was studied in 4,049 patients with rheumatoid arthritis (RA) in controlled andopen 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), 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 (including miliary, disseminated and extrapulmonary), 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 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 cytopaenia, 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® shouldnot 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.

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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.

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[1] K. Reich, A. Blauvelt, D. Thaçi, et al. Durability of Response in Certolizumab Pegol-Treated Patients Over 48 Weeks in CIMPASI-1 & 2 Trials. Presented at IFPA 2018, Stockholm, Sweden, June 27-30.

[2] A.B. Gottlieb, A. Blauvelt, D. Thaci, et al. Durable Reduction in Absolute PASI with Certolizumab Pegol in Patients with Chronic Plaque Psoriasis. Presented at IFPA 2018, Stockholm, Sweden, June 27-30.

[3] D. Thaci, A.B. Gottlieb, K. Reich, et al. Certolizumab Pegol Improves Patient-Reported Outcomes in Chronic Plaque Psoriasis Over 1 Year. Presented at IFPA 2018, Stockholm, Sweden, June 27-30.

[4] A.B. Gottlieb, A. Blauvelt, D. Thaci, et al. Durable Reduction in Absolute PASI with Certolizumab Pegol in Patients with Chronic Plaque Psoriasis. Presented at IFPA 2018, Stockholm, Sweden, June 27-30.

[5] K. Reich, A. Blauvelt, D. Thaci, et al. Certolizumab Pegol Is Effective for Chronic Plaque Psoriasis Across Patient Subgroups. Presented at IFPA 2018, Stockholm, Sweden, June 27-30.

[6] M. Lebwohl, A.S. Van Voorhees, M. Siegel, et al. A Comprehensive Survey Assessing the Family Planning Needs of Women with Psoriasis. Presented at IFPA 2018, Stockholm, Sweden, June 27-30.

[7] C. Ryan, C. Vandeloo, D. Munro, et al. The Psychosocial Impact of Psoriasis: Differential Experiences of Men and Women in Early Adulthood. Presented at IFPA 2018, Stockholm, Sweden, June 27-30.

[8] N. Bohme, A-D. Holst, F. Dybowski, et al. Coach@Home: A Support Program for Patients Treated With Certolizumab Pegol. Presented at IFPA 2018, Stockholm, Sweden, June 27-30.

[9] A. Sheahan, E. Lee, L. Pisenti, et al. Frequency of Inadequate Response to Treatment Among Psoriasis Patients on First-Line Biologics. Presented at IFPA 2018, Stockholm, Sweden, June 27-30.

[10] UCB Data on File.

[11] CIMZIA. Summary of Product Characteristics (SmPC), 2018.

[12] 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.

[13] 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.

[14] UCB Data on File.