



UCB Showcases Wealth of new Psoriasis Research at EADV 2019

- Data to be presented at EADV 2019 will further confirm the durability of CIMZIA® (certolizumab pegol) treatment in moderate-to-severe plaque psoriasis, including new three-year efficacy data
- New positive 60-week outcomes data from Phase 2 studies underscore the potential of bimekizumab to improve scalp and nail psoriasis and health-related quality of life in psoriasis patients
- In total, UCB will present nine abstracts at the meeting, demonstrating the company's ongoing commitment to improving the lives of people with psoriasis and psoriatic arthritis

Brussels, Belgium – 9 October 2019 – UCB, a global biopharmaceutical company, today announced new data on the use of the Fc-free anti-TNF treatment, CIMZIA® (certolizumab pegol), in psoriasis and psoriatic arthritis (PsA) will be presented at the 28th European Academy of Dermatology and Venereology congress (EADV) in Madrid, October 9-13, 2019. Data include three-year outcomes in psoriasisⁱ and four-year results in PsA from the open-label extension studies of CIMZIA.ⁱⁱ Additionally, the company will share 60-week results^{iii,iv} from the Phase 2 clinical development program of the company's pipeline molecule bimekizumab – a novel humanized monoclonal IgG1 antibody that potently and selectively neutralizes both IL-17A and IL-17F cytokines, thought to be key drivers of psoriasis.^v

“Results presented at EADV 2019 will reinforce and support the durability profile of CIMZIA efficacy in the treatment of both psoriasis and psoriatic arthritis, and provide further evidence as to the exciting potential of bimekizumab in psoriasis,” said Emmanuel Caeymaex, Head of Immunology and Executive Vice President, Immunology Patient Value Unit, UCB. “Patients with psoriasis deserve rapid and sustainable treatment results. The data we will share in Madrid show our commitment to delivering against these key patient needs.”

Reflecting UCB's efforts to better understand the impact of psoriasis on patients, and the unique needs of women, UCB will present new results from a sample of almost 90,000 respondents of the World Psoriasis Happiness Surveys. These findings highlight gender as a strong predictor of psychological and social well-being in people living with psoriasis and PsA, more so than geographies. The analysis illustrates how psoriasis and PsA can negatively affect women more than men when it comes to life satisfaction, loneliness, mood and self-esteem. Worse life satisfaction, stress, loneliness and isolation were felt most in young women with psoriasis.^{vi}

New CIMZIA three-year efficacy data in plaque psoriasis from a pooled analysis of the completed CIMPASI-1 and CIMPASI-2 open-label extension Phase 3 studies will be presented as an oral presentation at EADV 2019;ⁱ CIMZIA's safety profile remains consistent with previously reported data.ⁱ Additional pooled results from these trials include CIMZIA 48-week sustained efficacy data in psoriasis of the head and neck, areas where disease manifestations can cause high degrees of emotional distress, particularly for female patients.^{vii} A post-hoc analysis of the four-year RAPID-PsA study will also be highlighted, showing durability of response of CIMZIA in PsA.ⁱⁱ The ongoing focus on researching the long-term efficacy and safety of CIMZIA demonstrates how UCB continues its ongoing commitment to improving the lives of people with psoriasis.

New 60-week data on novel investigational molecule bimekizumab, from the BE ABLE Phase 2 clinical development program, will be shared in an oral presentation. The findings show rapid and sustained

improvements in quality of life (as measured by the Dermatology Life Quality Index), which positively associate with clinical outcomes in patients with moderate-to-severe plaque psoriasis.ⁱⁱⁱ Positive scalp and nail disease outcomes at 60 weeks will also be presented, further supporting bimekizumab's potential.^{iv}

The safety and efficacy of bimekizumab have not been established, and it is not approved by any regulatory authority worldwide.

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

UCB Sponsored Symposia:

Consider Tomorrow in Today's Treatment Choice for Women Living with Psoriasis, M. Augustin, S. McBride, A. Egeberg

- Date/Time: October 10, 2019: 17:00-18:30 CEST
- Location: Hall Sorolla

Uncovering the potential of IL-17A and IL-17F dual neutralization in psoriasis, K. Papp, A. Armstrong, L. Iversen

- Date/Time: October 11, 2019: 17:00-18:30 CEST
- Location: Hall Sorolla

CIMZIA Oral Presentations:

Certolizumab Pegol for Treatment of Plaque Psoriasis: Pooled Three-Year Efficacy Outcomes from the Intent-to-Treat Population of Two Phase 3 Trials (CIMPASI-1 and CIMPASI-2), K. Gordon, R. Warren, A. Gottlieb, A. Blauvelt, D. Thaçi, C. Leonardi, Y. Poulin, M. Boehnlein, S. Kavanagh, C. Arendt, K. Reich

- Date/Time: October 10, 2019: 11:35-11:45 CEST
- Location: N109-110

Body Mass Index and Systemic Corticosteroid Use as Indicators of Disease Burden and Their Influence on the Safety Profile of Certolizumab Pegol across Indications, A. Blauvelt, V. Bykerk, J. Curtis, C. Gaujoux-Viala, T. Kvien, W. Sandborn, K. Winthrop, C. Popova, X. Mariette

- Date/Time: October 10, 2019: 15:50-16:00 CEST
- Location: N109-110

CIMZIA e-Posters:

Durability of Response in Patients with Psoriatic Arthritis Treated with Certolizumab Pegol over 216 Weeks: Post-Hoc Analyses from the RAPID-PsA Study, A. Gottlieb, P. Gisondi, J. Eells, L. Peterson, A. Kavanaugh

Efficacy of Certolizumab Pegol for Psoriasis of the Head and Neck in Two Phase 3 Clinical Trials: CIMPASI-1 and CIMPASI-2, P. van de Kerkhof, A. Pinter, M. Boehnlein, S. Kavanagh, J. Crowley

Long-Term Efficacy of Certolizumab Pegol Dosed at 400 mg Every Two Weeks in Patients with Plaque Psoriasis: Pooled 128-Week Data from Two Phase 3 Trials (CIMPASI-1 and CIMPASI-2), K. Gordon, R. Warren, A. Gottlieb, A. Blauvelt, D. Thaçi, C. Leonardi, Y. Poulin, M. Boehnlein, S. Kavanagh, C. Arendt, K. Reich

Efficacy and Safety of Certolizumab Pegol in the Treatment of Japanese Patients With Psoriasis: Interim Week 24 Analyses from a 52-Week Phase 2/3, Randomised, Placebo-Controlled Study, A. Asahina, Y. Umezawa, S. Sakurai, N. Hoshii, H. Nakagawa

Bimekizumab Oral Presentations:

Bimekizumab provides rapid and sustained improvements in quality of life that correlate with clinical outcomes in patients with moderate to severe plaque psoriasis: 60-week results from a randomised, double-blinded, Phase 2b extension study, K. Papp, J. Merola, A. Gottlieb, C. Griffiths, K. Harris, N. Cross, L. Peterson, C. Cioffi, A. Blauvelt

- Date/Time: October 10, 2019: 10:25-10:35 CEST
- Location: N109-110

Bimekizumab e-Poster:

Bimekizumab provides rapid and sustained improvements in scalp and nail outcomes in patients with moderate-to-severe plaque psoriasis: 60-week results from a randomised, double-blinded, Phase 2b extension study, A. Blauvelt, K. Papp, J. Merola, A. Gottlieb, N. Cross, C. Madden, L. Peterson, C. Cioffi, C. Griffiths

UCB-Sponsored e-Poster on the Effect of Gender on the Impact of psoriasis:

Gender Differences in the Impact of Psoriasis: Results from the World Psoriasis Happiness Surveys, S. McBride, C. Ecoffet, F. Fierens, M. Birkjær

About Bimekizumab

Bimekizumab is an investigational novel humanized monoclonal IgG1 antibody that potently and selectively neutralizes both IL-17A and IL-17F, two key cytokines driving inflammatory processes.^{viii} IL-17A and IL-17F have similar 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 bimekizumab's dual neutralization of both IL-17A and IL-17F may provide a new targeted approach for the treatment of immune-mediated inflammatory diseases.^{v,viii,ix} Preclinical results in disease-relevant cells have shown that neutralizing IL-17F in addition to IL-17A reduces skin and joint inflammation, as well as pathological bone formation to an extent greater than inhibition of IL-17A alone.^{ix,x,xi}

The safety and efficacy of bimekizumab have not been established, and it 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 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 μ g/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 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® 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 2019. https://www.ema.europa.eu/documents/product-information/cimzia-epar-product-information_en.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 and neurology. With 7,500 people in approximately 40 countries, the company generated revenue of € 4.6 billion in 2018. 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 Gordon K, et al. Certolizumab Pegol for Treatment of Plaque Psoriasis: Pooled Three-Year Efficacy Outcomes from the Intent-to-Treat Population of Two Phase 3 Trials (CIMPASI-1 and CIMPASI-2). Abstract to be presented at EADV 2019, 9-13 October, Madrid Spain.

ⁱⁱ Gottlieb A, et al. Durability of Response in Patients with Psoriatic Arthritis Treated with Certolizumab Pegol over 216 Weeks: Post-Hoc Analyses from the RAPID-PsA Study. Abstract to be presented at EADV 2019, 9-13 October, Madrid Spain.

ⁱⁱⁱ Papp K, et al. Bimekizumab provides rapid and sustained improvements in quality of life that correlate with clinical outcomes in patients with moderate to severe plaque psoriasis: 60-week results from a randomised, double-blinded, Phase 2b extension study. Abstract to be presented at EADV 2019, 9-13 October, Madrid Spain.

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- ^{iv} Blauvelt A, et al. Bimekizumab provides rapid and sustained improvements in scalp and nail outcomes in patients with moderate-to-severe plaque psoriasis: 60 week results from a randomised, double-blinded, Phase 2b extension study. Abstract to be presented at EADV 2019, 9-13 October, Madrid Spain.
 - ^v 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.* 2018;77:523-532.
 - ^{vi} McBride S, et al. Gender Differences in the Impact of Psoriasis: Results from the World Psoriasis Happiness Surveys. Abstract to be presented at EADV 2019, 9-13 October, Madrid Spain.
 - ^{vii} van de Kerkhof P, et al. Efficacy of Certolizumab Pegol for Psoriasis of the Head and Neck in Two Phase 3 Clinical Trials: CIMPASI-1 and CIMPASI-2. Abstract to be presented at EADV 2019, 9-13 October, Madrid Spain.
 - ^{viii} Glatt S, Helmer E, Haier B, et al. First-in-human randomized study of bimekizumab, a humanized monoclonal antibody and selective dual inhibitor of IL-17A and IL-17F, in mild psoriasis. *Br J Clin Pharmacol.* 2017;83(5):991-1001.
 - ^{ix} Papp K, Merola J, Gottlieb A, Griffiths C, Cross N, Peterson L, Cioffi C, Blauvelt A. Dual neutralization of both interleukin 17A and interleukin 17F with bimekizumab in patients with psoriasis: Results from BE ABLE 1, a 12-week randomized, double-blinded, placebo-controlled phase 2b trial. *J Am Acad Dermatol.* 2018;79(2):277-286.e10.
 - ^x 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).
 - ^{xi} 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;76(suppl.2):213-213.