



## **UCB Presents New Long-Term Data Showing Substantial Impact for CIMZIA® (Certolizumab Pegol) in Axial Spondyloarthritis and Rheumatoid Arthritis and Late-Breaking Bimekizumab Data in Psoriatic Arthritis**

- Oral presentation of results from C-AXSPAND, the first Phase 3 study to follow non-radiographic axial spondyloarthritis (nr-axSpA) patients for 52 weeks, demonstrated positive results for CIMZIA® (certolizumab pegol) in this patient population when added to common background medications
- In the first presentation of long-term data for the investigational product bimekizumab, late-breaking results from the Phase 2b BE ACTIVE study in active psoriatic arthritis (PsA) over 48 weeks demonstrated maintenance of substantial improvements across both skin and joint outcomes, reinforcing the potential value of the molecule's unique dual neutralization of IL-17A and IL-17F
- Results from the run-in phase of the C-OPTIMISE study show that patients with nr-axSpA and ankylosing spondylitis (AS), achieved sustained remission with CIMZIA
- A disease state presentation on the treatment patterns of women of childbearing age shows the need for additional awareness and use of appropriate treatment options for family planning and throughout the patient treatment journey

**Brussels, Belgium – 19 October 2018** – UCB, a global biopharmaceutical company, is presenting data highlighting the potential value of CIMZIA® (certolizumab pegol) and one of its key pipeline molecules, bimekizumab, across patient populations, including those living with conditions across the entire axial spondyloarthritis (axSpA) spectrum, psoriatic arthritis (PsA) and rheumatoid arthritis (RA). Additional research is focused on women of childbearing age with chronic inflammatory disease. Findings will be presented at the American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting on October 19-24, in Chicago, Illinois.

Results from an investigational study, C-AXSPAND, the first Phase 3, multicenter, double-blind, placebo-controlled study to evaluate non-radiographic axSpA (nr-axSpA) patients for 52 weeks, will be presented in an oral session. CIMZIA demonstrated clinically relevant and statistically significant improvements in patients with active disease and objective signs of inflammation, as measured by major improvement in Ankylosing Spondylitis Disease Activity Score (ASDAS-MI), despite previous use of non-steroidal anti-inflammatory drugs (NSAIDs), providing clear evidence of the limitations of common background medications. The first 52 weeks of the study have been completed and an additional two years of safety follow-up are ongoing. CIMZIA is not approved for the treatment of nr-axSpA by the U.S. Food and Drug Administration (FDA).

Interim results from the Phase 2b BE ACTIVE study, assessing the dose response, long-term efficacy and safety of the investigational molecule bimekizumab in the treatment of active PsA, will be presented as

part of an oral session. Data suggest that bimekizumab substantially improved joint and skin measures through 48 weeks, providing further evidence to support that neutralizing IL-17F in addition to IL-17A is a promising therapeutic approach in patients with active PsA. Bimekizumab is an investigational molecule which has not been approved by any regulatory agency worldwide.

“The studies presented this week at ACR/ARHP 2018 represent the potential for CIMZIA to treat multiple patient populations and further demonstrate our commitment to providing optimal disease management solutions, particularly for patients living with psoriatic arthritis and conditions across the entire axSpA disease spectrum. We are also presenting research that contributes to improved understanding of the treatment needs for women of childbearing age with chronic inflammatory disease,” said Emmanuel Caeymaex, Head of Immunology and Executive Vice President of UCB’s Immunology Patient Value Unit. “UCB is committed to partnering with rheumatologists, patient advocacy groups, regulators and other healthcare professionals to advance and optimize clinical care to these underserved patient populations by objectively addressing patient needs through innovative solutions and therapies like the investigational molecule bimekizumab, an IL-17A and IL-17F inhibitor.”

Additional presentations include results from the first 48 weeks of the 96-week C-OPTIMISE study investigating treatment outcomes in nr-axSpA and AS. Positive results from Part A of this study showed that when treated with CIMZIA, a substantial proportion of patients across the axSpA spectrum achieved sustained remission (ASDAS <1.3). The percentage of those who achieved sustained remission was similar between AS and nr-axSpA patients.

Additionally, ÉCLAIR, a prospective, observational, multicenter study of clinical outcomes in a routine clinical practice setting found that rheumatoid arthritis patients treated with CIMZIA experienced disease improvements at 12 months, which were sustained up to 36 months.

An additional disease state presentation using U.S. claims data will highlight trends of lower biologic utilization in women of childbearing age (18-44 years) living with rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis compared to men in the same age group, despite the importance of maintaining disease control during periods of reproductive potential.

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

##### Presentations on CIMZIA® in Approved Indications:

#### **(286) The Prevalence and Treatment Patterns of Women of Childbearing Age with Rheumatic Disease:**

Edward Lee, Robert Suruki, Brian Carpenter, Ty Harkness, Daniel Luk, and Mohamed Yassine

- Date/Time: October 21, 2018, 9:00AM CT
- Presentation Type: ePoster
- Location: McCormick Place, Poster Hall F2

#### **(2516) Long-Term Maintenance of Response in Patients with Rheumatoid Arthritis Treated with**

**Certolizumab Pegol:** Alain Saraux, Rene-Marc Flipo, Francis Fagnani, Gabrielle Cukierman, Isabelle Bru, Jean-Michel Joubert, Jan-Christof Schuller, Jacque Massol and Bernard Combe

- Date/Time: October 23, 2018, 9:00AM CT

- Presentation Type: ePoster
- Location: McCormick Place, Poster Hall F2

#### Investigational Presentations on CIMZIA:

**(1868) Efficacy and Safety Outcomes in Patients with Non-Radiographic Axial Spondyloarthritis Treated with Certolizumab Pegol: Results from the First 52-Week Randomized Placebo-Controlled Study (NCT02552212):** Atul Deodhar, Lianne S. Gensler, Jonathan Kay, Walter P. Maksymowych, Nigil Haroon, Robert Landewé, Martin Rudwaleit, Stephen Hall, Lars Bauer, Bengt Hoepken, Natasha de Peyrecave, Brian Kilgallen, Désirée van der Heijde

- Date/Time: October 22, 2018, 3:30PM CT
- Presentation Type: Oral Session
- Location: McCormick Place, W375a

**(2558) Efficacy and Safety Outcomes in Patients with Axial Spondyloarthritis Treated with Certolizumab Pegol: Results from the 48-Week Run-In Part of a 96-Week Study (NCT02505542):** Robert Landewé, Désirée van der Heijde, Maxime Dougados, Xenofon Baraliakos, Filip Van den Bosch, Bengt Hoepken, Karen Thomas, Lianne S. Gensler

- Date/Time: October 23, 2018, 9:00AM CT
- Presentation Type: ePoster
- Location: McCormick Place, Poster Hall F2

#### Presentations on UCB's Investigational Pipeline:

##### Bimekizumab

**(L17) Dual Neutralization of IL-17A and IL-17F With Bimekizumab in Patients with Active PsA: Results From A 48-Week Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study:** Christopher Ritchlin, Arthur Kavanaugh, Joseph F. Merola, Georg Schett, Jose U. Scher, Richard B. Warren, Deepak Assudani, Thomas Kumke, Barbara Ink, Ian McInnes

- Date/Time: October 23, 2018, 4:40 PM – 4:55PM CT
- Presentation Type: Oral
- Location: McCormick Place, W375c

#### **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. 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 unique dual neutralization of both IL-17A and IL-17F may provide a new targeted approach for the treatment of immune-mediated inflammatory diseases.<sup>i,ii,iii</sup> 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.<sup>ii,iv,v</sup>

UCB is also studying bimekizumab in other disease areas, including psoriasis and ankylosing spondylitis. The safety and efficacy of bimekizumab have not been established, and it is not approved by any regulatory authority worldwide.

### **About CIMZIA® in the US**

CIMZIA® is the only Fc-free, PEGylated anti-TNF (Tumor Necrosis Factor). CIMZIA® has a high affinity for human TNF-alpha, selectively neutralizing the pathophysiological effects of TNF-alpha.

CIMZIA® is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), adults with active psoriatic arthritis (PsA), and adults with active ankylosing spondylitis (AS). CIMZIA is also indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

In addition, it is indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. See important safety information, including risk of serious bacterial, viral and fungal infections and tuberculosis below.

### **Important Safety Information about CIMZIA® in the US**

#### **CONTRAINDICATIONS**

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylactoid reaction, serum sickness, and urticaria.

#### **SERIOUS INFECTIONS**

**Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.**

**Discontinue CIMZIA if a patient develops a serious infection or sepsis.**

**Reported infections include:**

- **Active tuberculosis (TB), including reactivation of latent TB.** Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before CIMZIA use and during therapy. Initiate treatment for latent TB prior to CIMZIA use.
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis.** Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

**Carefully consider the risks and benefits of treatment with CIMZIA prior to initiating therapy in the following patients: with chronic or recurrent infection; who have been exposed to TB; with a history of opportunistic infection; who resided in or traveled in regions where mycoses are endemic; with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.**

- Do not start CIMZIA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.

## **MALIGNANCY**

**Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.**

- Consider the risks and benefits of CIMZIA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among CIMZIA-treated patients compared to control patients.
- In CIMZIA clinical trials, there was an approximately 2-fold higher rate of lymphoma than expected in the general U.S. population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk of lymphoma than the general population.
- Malignancies, some fatal, have been reported among children, adolescents, and young adults being treated with TNF blockers. Approximately half of the cases were lymphoma, while the

rest were other types of malignancies, including rare types associated with immunosuppression and malignancies not usually seen in this patient population.

- Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including CIMZIA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treating with CIMZIA in these patient types.
- Cases of acute and chronic leukemia were reported with TNF blocker use.

#### **HEART FAILURE**

- Worsening and new onset congestive heart failure (CHF) has been reported with TNF blockers. Exercise caution and monitor carefully.

#### **HYPERSENSITIVITY**

- Angioedema, anaphylactoid reaction, dyspnea, hypotension, rash, serum sickness, and urticaria have been reported following CIMZIA administration. If a serious allergic reaction occurs, stop CIMZIA and institute appropriate therapy. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a plastic derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

#### **HEPATITIS B VIRUS REACTIVATION**

- Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Test patients for HBV infection before initiating treatment with CIMZIA.
- Exercise caution in patients who are carriers of HBV and monitor them before and during CIMZIA treatment.
- Discontinue CIMZIA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming CIMZIA after HBV treatment.

#### **NEUROLOGIC REACTIONS**

- TNF blockers, including CIMZIA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, seizure disorder, optic neuritis, peripheral neuropathy, and Guillain-Barré syndrome.

#### **HEMATOLOGIC REACTIONS**

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with CIMZIA.
- Consider stopping CIMZIA if significant hematologic abnormalities occur.

#### DRUG INTERACTIONS

- Do not use CIMZIA in combination with other biological DMARDs.

#### AUTOIMMUNITY

- Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

#### IMMUNIZATIONS

- Patients on CIMZIA should not receive live or live-attenuated vaccines.

#### ADVERSE REACTIONS

- The most common adverse reactions in CIMZIA clinical trials ( $\geq 8\%$ ) were: upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

For full prescribing information, please visit [www.ucb-usa.com](http://www.ucb-usa.com).

#### 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 $\alpha$  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 $\alpha$ , 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  $\mu\text{g/ml}$  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 herpes zoster, 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, angioedema, 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 July 2018.

[https://www.ema.europa.eu/documents/product-information/cimzia-epar-product-information\\_en.pdf](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](http://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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<sup>i</sup> 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 May;83(5):991-1001. doi: 10.1111/bcp.13185. Epub 2017 Jan 10.

<sup>ii</sup> 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 Aug;79(2):277-286.e10. <https://www.ncbi.nlm.nih.gov/pubmed/29609013>

<sup>iii</sup> 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*. <https://www.ncbi.nlm.nih.gov/pubmed/29275332>.

<sup>iv</sup> 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). UCB Data on File. July 2017.

<sup>v</sup> 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*. 201706;76 (suppl.2):213-213.