



## UCB Advances Psoriasis Pipeline with Positive Data at American Academy of Dermatology Annual Meeting (AAD 2018)

- Oral presentation of Phase 2b findings for bimekizumab in the treatment of moderate-to-severe chronic plaque psoriasis patients will focus on the effects of dual neutralization of both IL-17A and IL-17F
- Three pooled sub-analyses from ongoing, Phase 3 studies CIMPASI-1, CIMPASI-2 and CIMPACT reflect potential versatility of CIMZIA® (certolizumab pegol) in the treatment of psoriasis
- Results from the largest cohort of pregnant women exposed to an anti-TNF for management of a chronic inflammatory disease highlight the value of CIMZIA for this underserved population

**Brussels, Belgium – February 16, 2018** – UCB, a global biopharmaceutical company, will be presenting new data on CIMZIA® (certolizumab pegol) and one of UCB’s key pipeline molecules, bimekizumab, at the 2018 American Academy of Dermatology (AAD) Annual Meeting in San Diego, CA (February 16-20, 2018).

“UCB is thrilled to participate in the important scientific exchange at AAD this week and to translate our learnings into improved patient care. We are committed to patients with psoriatic disease, through investment in underserved areas and breakthrough solutions that deliver unique outcomes,” said Emmanuel Caeymaex, Head of Immunology and Executive Vice President at UCB. “As our research at AAD shows, UCB is executing on its Patient Value Strategy to connect the unmet needs of patients with innovative science. People living with psoriasis often face a heavy disease burden and may experience significant physical discomfort. The studies presented this week explore the potential value of CIMZIA for psoriasis patient subpopulations, as well as the development of new approaches to treating inflammation associated with psoriasis, such as the neutralization of both IL-17A and IL-17F with bimekizumab.”

Full efficacy and safety findings from the Phase 2b BE ABLE study on the investigational molecule bimekizumab will highlight the dual neutralization of IL-17A and IL-17F, two key cytokines driving the inflammatory processes, as a novel and effective targeting approach in psoriasis. In July 2017, UCB announced positive topline results from the BE ABLE study demonstrating that 79% of patients achieved at least 90% skin clearance in the psoriasis area and severity index (PASI90) and up to 60% of patients achieved complete skin clearance (PASI100) at week 12.

Additional data highlights include presentations on the treatment effect of CIMZIA in adults with moderate-to-severe chronic plaque psoriasis. Results will be presented from a pooled sub-analysis of the ongoing, Phase 3 studies CIMPASI-1, CIMPASI-2 and CIMPACT, exploring the effect of CIMZIA in psoriasis patients who had been previously exposed to systemic therapy, including biologics. A separate



pooled sub-analysis of the three studies analyzes the potential treatment effect across demographic and baseline disease subgroups, including age, gender, weight/BMI, and disease severity. A third sub-analysis explores the treatment effect of CIMZIA in psoriasis patients both with and without self-reported concurrent psoriatic arthritis. CIMZIA is not currently approved by the U.S. Food and Drug Administration or other health authorities to treat psoriasis.

Prospective and retrospective data showcasing the characteristics and outcomes from 1,541 maternal CIMZIA-exposed pregnancies -- the largest cohort of pregnant women exposed to an anti-TNF for management of a chronic inflammatory disease -- will also be presented this week. Women surveyed in this study were living with psoriatic arthritis, Crohn's disease, rheumatoid arthritis, and ankylosing spondylitis, among others (excluding psoriasis).

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

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

##### Bimekizumab

#### **[F061] Dual Neutralization of Interleukin (IL)-17A and IL-17F with Bimekizumab in Moderate-to-severe Psoriasis: Results from a Phase 2b, Randomized, Double-blinded, Placebo-controlled, Dose-ranging Study**

**Papp, K. A. *et al.***

- Date/Time: Saturday, February 17 at 1:00 PM - 3:00 PM PT
- Session Information: Late-breaking Research: Clinical Trials - Ballroom 20A

#### **Presentations on Investigational Studies of CIMZIA®**

##### Psoriasis

#### **[7774] Certolizumab Pegol is Effective for Chronic Plaque Psoriasis Regardless of Previous Exposure to Systemic Therapy: A Pooled Subanalysis of Ongoing, Phase 3 Studies (CIMPASI-1, CIMPASI-2, CIMPACT)**

**Blauvelt, A. *et al.***

- Date/Time: Friday, February 16 at 7:00AM PT
- Session Information: ePoster only



**[7692] Certolizumab Pegol is Effective for Chronic Plaque Psoriasis Across Patient Subgroups: A Pooled Subanalysis From Ongoing, Phase 3 Studies (CIMPASI-1, CIMPASI-2, CIMPACT)**

**Reich, K. *et al.***

- Date/Time: Saturday, February 17 at 4:35 PM - 4:40 PM PT
- Session Information: ePoster Presentation Center 1

**[7773] A Pooled Subanalysis of the Efficacy of Certolizumab Pegol in Patients with Self-Reported Psoriatic Arthritis in Ongoing, Phase 3 Psoriasis Studies (CIMPASI-1, CIMPASI-2, CIMPACT)**

**Gottlieb, A. B. *et al.***

- Date/Time: Friday, February 16 at 7:00AM PT
- Session Information: ePoster only

Women of Childbearing Age

**[7094] Characteristics and Outcomes of Prospectively Reported Pregnancies Exposed to Certolizumab Pegol from a Safety Database**

**Kimball, A. B. *et al.***

- Date/Time: Friday, February 16 at 1:10 PM - 1:15PM PT
- Session Information: ePoster Presentation Center 1

**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 dual neutralization of both IL-17A and IL-17F 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.<sup>i,ii,iii</sup>

UCB is studying bimekizumab in psoriasis, psoriatic arthritis and ankylosing spondylitis. Bimekizumab 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, adults with active psoriatic arthritis (PsA), and adults with active ankylosing spondylitis (AS). In addition, it is indicated for reducing signs and symptoms of Crohn's disease 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**

#### **Risk of Serious Infections and Malignancy**

**Patients treated with Cimzia® are at an 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. Cimzia® should be discontinued if a patient develops a serious infection or sepsis. Reported infections include:**

- **Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before Cimzia® use and during therapy. Treatment for latent infection should be initiated 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. Empiric anti-fungal therapy should be considered 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.**

**The risks and benefits of treatment with Cimzia® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Cimzia®, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.**

**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.**



Patients treated with Cimzia® are at an increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death. Opportunistic infections due to bacterial, mycobacterial, invasive fungal, viral, parasitic, or other opportunistic pathogens including aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, legionellosis, listeriosis, pneumocystosis and tuberculosis have been reported with TNF blockers. Patients have frequently presented with disseminated rather than localized disease.

Treatment with Cimzia® should not be initiated in patients with an active infection, including clinically important localized infections. Cimzia® should be discontinued if a patient develops a serious infection or sepsis. Patients greater than 65 years of age, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants (e.g., corticosteroids or methotrexate) may be at a greater risk of infection. Patients who develop a new infection during treatment with Cimzia® should be closely monitored, undergo a prompt and complete diagnostic workup appropriate for immunocompromised patients, and appropriate antimicrobial therapy should be initiated. Appropriate empiric antifungal therapy should also be considered while a diagnostic workup is performed for patients who develop a serious systemic illness and reside or travel in regions where mycoses are endemic.

### **Malignancies**

During controlled and open-labeled portions of Cimzia® studies of Crohn's disease and other diseases, malignancies (excluding non-melanoma skin cancer) were observed at a rate of 0.5 per 100 patient-years among 4,650 Cimzia®-treated patients versus a rate of 0.6 per 100 patient-years among 1,319 placebo-treated patients. In studies of Cimzia® for Crohn's disease and other investigational uses, there was one case of lymphoma among 2,657 Cimzia®-treated patients and one case of Hodgkin lymphoma among 1,319 placebo-treated patients. In Cimzia® RA clinical trials (placebo-controlled and open label), a total of three cases of lymphoma were observed among 2,367 patients. This is approximately 2-fold higher than expected in the general population. Patients with RA, particularly those with highly active disease, are at a higher risk for the development of lymphoma. The potential role of TNF blocker therapy in the development of malignancies is not known.

Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blocking agents (initiation of therapy ≤18 years of age), of which Cimzia® is a member. Approximately half of the cases were lymphoma (including Hodgkin's and non-Hodgkin's lymphoma), while the other cases represented a variety of different malignancies and included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents. Most of the patients were receiving concomitant immunosuppressants.

Cases of acute and chronic leukemia have been reported with TNF-blocker use. Even in the absence of TNF-blocker therapy, patients with RA may be at a higher risk (approximately 2-fold) than the general population for developing leukemia.

Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma that has a very aggressive disease course and is usually fatal, have been reported in patients treated with TNF blockers, including Cimzia®. The majority of reported TNF blocker cases occurred in adolescent and young adult males with Crohn's disease or ulcerative colitis. Almost all of these patients had received



treatment with the immunosuppressants azathioprine and/or 6-mercaptopurine (6-MP) concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treatment with Cimzia®, especially in these patient types.

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-antagonists, including Cimzia®. Periodic skin examinations are recommended for all patients, particularly those with risk factors for skin cancer.

### **Heart Failure**

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers. Cimzia® has not been formally studied in patients with CHF. Exercise caution when using Cimzia® in patients who have heart failure and monitor them carefully.

### **Hypersensitivity**

Symptoms compatible with hypersensitivity reactions, including angioedema, dyspnea, hypotension, rash, serum sickness, and urticaria, have been reported rarely following Cimzia® administration. Some of these reactions occurred after the first administration of Cimzia®. If such reactions occur, discontinue further administration of Cimzia® and institute appropriate therapy.

### **Hepatitis B Reactivation**

Use of TNF blockers, including Cimzia®, has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. Some cases have been fatal. Test patients for HBV infection before initiating treatment with Cimzia®. Exercise caution in prescribing Cimzia® for patients identified as carriers of HBV, with careful evaluation and monitoring prior to and during treatment. In patients who develop HBV reactivation, discontinue Cimzia® and initiate effective anti-viral therapy with appropriate supportive treatment.

### **Neurologic Reactions**

Use of TNF blockers, including Cimzia®, has been associated with rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disease, including multiple sclerosis, and with peripheral demyelinating disease, including Guillain-Barré syndrome. Rare cases of neurological disorders, including seizure disorder, optic neuritis, and peripheral neuropathy have been reported in patients treated with Cimzia®. Exercise caution in considering the use of Cimzia® in patients with these disorders.

### **Hematologic Reactions**

Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia (e.g., leukopenia, pancytopenia, thrombocytopenia) has been infrequently reported with Cimzia®. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on Cimzia®. Consider discontinuation of Cimzia® therapy in patients with confirmed significant hematologic abnormalities.



## Drug Interactions

An increased risk of serious infections has been seen in clinical trials of other TNF blocking agents used in combination with anakinra or abatacept. Formal drug interaction studies have not been performed with rituximab or natalizumab; however, because of the nature of the adverse events seen with these combinations with TNF blocker therapy, similar toxicities may also result from the use of Cimzia® in these combinations. Therefore, the combination of Cimzia® with anakinra, abatacept, rituximab, or natalizumab is not recommended. Interference with certain coagulation assays has been detected in patients treated with Cimzia®. There is no evidence that Cimzia® therapy has an effect on in vivo coagulation. Cimzia® may cause erroneously elevated aPTT assay results in patients without coagulation abnormalities.

## Autoimmunity

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

## Immunizations

Do not administer live vaccines or live-attenuated vaccines concurrently with Cimzia®.

## Adverse Reactions

In controlled Crohn's clinical trials, the most common adverse events that occurred in  $\geq 5\%$  of Cimzia® patients (n=620) and more frequently than with placebo (n=614) were upper respiratory infection (20% Cimzia®, 13% placebo), urinary tract infection (7% Cimzia®, 6% placebo), and arthralgia (6% Cimzia®, 4% placebo). The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 8% for Cimzia® and 7% for placebo.

In controlled RA clinical trials, the most common adverse events that occurred in  $\geq 3\%$  of patients taking Cimzia® 200 mg every other week with concomitant methotrexate (n=640) and more frequently than with placebo with concomitant methotrexate (n=324) were upper respiratory tract infection (6% Cimzia®, 2% placebo), headache (5% Cimzia®, 4% placebo), hypertension (5% Cimzia®, 2% placebo), nasopharyngitis (5% Cimzia®, 1% placebo), back pain (4% Cimzia®, 1% placebo), pyrexia (3% Cimzia®, 2% placebo), pharyngitis (3% Cimzia®, 1% placebo), rash (3% Cimzia®, 1% placebo), acute bronchitis (3% Cimzia®, 1% placebo), fatigue (3% Cimzia®, 2% placebo). Hypertensive adverse reactions were observed more frequently in patients receiving Cimzia® than in controls. These adverse reactions occurred more frequently among patients with a baseline history of hypertension and among patients receiving concomitant corticosteroids and non-steroidal anti-inflammatory drugs. Patients receiving Cimzia® 400 mg as monotherapy every 4 weeks in RA controlled clinical trials had similar adverse reactions to those patients receiving Cimzia® 200 mg every other week. The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 5% for Cimzia® and 2.5% for placebo.

The safety profile for patients with Psoriatic Arthritis (PsA) treated with CIMZIA® was similar to the safety profile seen in patients with RA and previous experience with Cimzia®.



# UCB News

The safety profile for AS patients treated with Cimzia® was similar to the safety profile seen in patients with RA.

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

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 of the immune system or of the central nervous system. With more than 7 500 people in approximately 40 countries, the company generated revenue of € 4.2 billion in 2016. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: [@UCB\\_news](https://twitter.com/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, Baeten D, Baker T, et al. Dual IL-17A and IL-17F neutralisation by bimekizumab in psoriatic arthritis: evidence from preclinical experiments and a randomized placebo-controlled clinical trial that IL-17F contributes to human chronic tissue inflammation. *Ann Rheum Dis*. In Press.

<sup>ii</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>iii</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*. 2017;76 (suppl.2):213-213.