

## UCB Presents Nine Abstracts at EADV 2020, Showcasing Ongoing Commitment to Dermatology

- First results from the Phase 3 BE SURE study will be presented showing superior skin clearance with bimekizumab compared to Humira® (adalimumab) in patients with moderate-to-severe plaque psoriasis
- Two oral presentations from the Phase 3 BE VIVID study show consistent levels of skin clearance with bimekizumab irrespective of patient demographics, disease characteristics and prior treatment experience, and an acceptable safety profile based on an integrated analysis across Phase 2 and Phase 3 psoriasis trials
- Two e-posters show complete clearance with bimekizumab in high impact areas: scalp, nails, palms and soles, and that disease control with bimekizumab translates to substantial improvements in health-related quality of life
- New data also showcase the long-term quality of life improvements that are possible for psoriasis patients through treatment with CIMZIA® (certolizumab pegol)

**Brussels, Belgium – October 29, 2020** – UCB, a global biopharmaceutical company, today announced that new data on the investigational IL-17A and IL-17F inhibitor, bimekizumab, and TNF inhibitor, CIMZIA® (certolizumab pegol), in the management of moderate-to-severe plaque psoriasis are being presented at the European Academy of Dermatology and Venereology (EADV) Congress, taking place virtually on October 29-31, 2020.

The first presentation of the Phase 3 BE SURE study results demonstrates the superior levels of psoriasis skin clearance observed with bimekizumab treatment, as compared to adalimumab until week 24, the durability of bimekizumab's response to week 56, and the rapid increase in rates of skin clearance in patients switching from adalimumab to bimekizumab.<sup>1</sup>

"We are excited to share the bimekizumab BE SURE study results, further results from the BE VIVID study, plus new pooled safety data. These studies further demonstrate the rationale for inhibiting IL-17F in addition to IL-17A. The data also show that bimekizumab has the potential to raise the treatment bar with respect to speed, depth and durability of response for psoriasis patients and dermatologists, if approved by health authorities. We are also presenting long-term results from our CIMPASI-1 and CIMPASI-2 clinical program for CIMZIA®, and support for our ongoing commitment to addressing the unmet needs of patients living with psoriatic disease. EADV represents an opportunity for UCB to demonstrate its ongoing commitment to delivering innovative solutions to help meet the needs of the dermatology community," said Emmanuel Caeymaex, Executive Vice President Immunology Solutions and Head of US, UCB.

UCB is sharing data from further analyses of the Phase 3 BE VIVID study investigating bimekizumab's effect on high impact areas that can be most burdensome to psoriasis patients, complete skin clearance across different baseline demographics and treatment experience and the impact of bimekizumab treatment on health-related quality of life. The results show:

- Complete clearance of scalp, nail and psoriasis of the palms of hands and feet was observed in a higher proportion of bimekizumab-treated patients with moderate-to-severe disease versus the study comparator, Stelara® (ustekinumab) at weeks 16 and 52.<sup>2</sup>
- Bimekizumab provided similar levels of complete skin clearance, as measured by the proportion of patients achieving a 100 percent improvement in the Psoriasis Area and Severity Index (PASI 100), up to one year in patients with moderate-to-severe disease regardless of weight, baseline disease severity or prior treatment exposure.<sup>3</sup>
- Lasting skin clearance translates to rapid and sustained improvements in quality of life.<sup>4</sup> Increased disease control seen with bimekizumab treatment, compared with ustekinumab, translated to greater quality of life as measured by the Dermatology Life Quality Index (DLQI).<sup>4</sup> After one year of treatment with bimekizumab, almost 70 percent of patients achieved complete skin clearance and reported no impact of psoriasis on their quality of life, versus 40 percent with ustekinumab.<sup>4</sup>

Other results being presented at the virtual meeting include a pooled short and longer-term safety analysis across Phase 2 and Phase 3 clinical trials of bimekizumab in patients with moderate-to-severe plaque psoriasis. The majority of treatment emergent adverse events (TEAEs) were mild-to-moderate in severity and discontinuations were low.<sup>5</sup> In general, the exposure-adjusted incidence rates (EAIRs) of TEAEs and TEAEs of interest did not increase with bimekizumab exposure duration. The vast majority of candida infections were oral, mild-to-moderate, and did not lead to treatment discontinuation.<sup>5</sup>

UCB is also sharing long-term psoriasis quality of life data for certolizumab pegol. Pooled data from CIMPASI-1 and CIMPASI-2 Phase 3 trials show that rapid improvements in health-related quality of life were seen as early as week 8 after treatment with certolizumab pegol. These positive treatment effects were generally durable to week 144.<sup>6,7</sup>

In efforts to better understand the unmet needs of women of childbearing age living with psoriatic disease, UCB conducted a survey of attitudes towards family planning amongst ~600 (n=573) women from 11 European countries. Survey results will be presented, showing that those surveyed reported considerable negative impact on family planning and pregnancy due to psoriasis and/or psoriatic arthritis. A large proportion also reported dissatisfaction with their support networks, highlighting an unmet need in this patient population.<sup>8</sup>

Findings of a new survey into the competencies of dermatologists practicing in Germany, UK and the U.S. are also being presented. Results demonstrated that interventions which may provide opportunities to enhance care include education about optimal risk assessment, treatment and management of women of childbearing age with chronic inflammatory diseases and support for shared decision making.<sup>9</sup> Findings also showed that overall shared decision making was uncommon due to a lack of knowledge, skills and attitude.<sup>9</sup>

#### Following is a guide to the UCB data presentations:

##### **Bimekizumab Oral Presentations:**

**Bimekizumab efficacy and safety versus adalimumab in patients with moderate to severe plaque psoriasis: Results from a multicentre, randomised, double-blinded active comparator-controlled phase 3 trial (BE SURE),** R. Warren, A. Blauvelt, J. Bagel, K. Papp, P. Yamauchi, A. Armstrong, R. Langley, V. Vanvoorden, L. Peterson, D. de Cuyper, N. Cross, K. Reich

**Bimekizumab versus ustekinumab efficacy across subgroups of patients with moderate to severe plaque psoriasis: Results from the multicentre, randomised, double-blinded phase 3 BE VIVID trial,** B. Strober, J. Krueger, N. Magnolo, R. Vender, D. Toth, D. Thaçi, M. Wang, C. Cioffi, C. Madden, R. Warren

**Bimekizumab safety in patients with moderate to severe psoriasis: Analysis of pooled data from phase 2 and 3 clinical trials,** K. Reich, A. Blauvelt, M. Lebwohl, K. Papp, P. Rich, B. Strober, D. de Cuyper, C. Madden, L. Peterson, V. Vanvoorden, R. Warren

##### **Bimekizumab e-Posters:**

**Bimekizumab for the treatment of moderate to severe plaque psoriasis with scalp, nail and palmoplantar involvement through 52 weeks: Post-hoc analysis from the BE VIVID phase 3 trial,** K. Papp, M. Lebwohl, A. Gottlieb, M. Sebastian, R. Langley, Y. Okubo, M. Wang, C. Cioffi, F. Staelens, K. Reich

**Bimekizumab versus ustekinumab in plaque psoriasis: Lasting efficacy translates to rapid and sustained improvements in quality of life in the BE VIVID multicentre, randomised, double-blinded phase 3 trial,** K. Gordon, P. Foley, P. Rich, K. Duffin, A. Pinter, C. Griffiths, M. Wang, V. Vanvoorden, F. Staelens, V. Ciaravino, J. Merola

##### **CIMZIA e-Posters:**

**Long-term improvements in health-related quality of life of patients with moderate to severe plaque psoriasis treated with certolizumab pegol: Results from the CIMPASI-1 and CIMPASI-2 phase 3 trials,** D. Thaçi, A. Blauvelt, K. Reich, R. Warren, V. Piguet, F. Brock, F. Fierens, V. Ciaravino, M. Lebwohl

**Durability of Certolizumab Pegol in Patients with Psoriasis or Rheumatoid Arthritis Over Three Years: An Analysis of Pooled Clinical Trial Data,** A. Blauvelt, A. Gottlieb, K. Reich, Y. Tanaka, K. Winthrop, C. Popova, N. Tilt, V. Bykerk

### **UCB-Sponsored e-Poster:**

**Impact of Psoriatic Disease on Family Planning in Women Aged 18–45: Results from a Multinational Survey across 11 Countries in Europe,** S. McBride, M. Fargnoli, A. Fougousse, M. Bustinduy, L. Catton, L. Senturk, C. Ecoffet, J. Koren, A. Titalii

*Humira® is a registered trademark of AbbVie, Inc; Stelara® is a registered trademark of Johnson & Johnson.*

### **About Bimekizumab**

Bimekizumab is an investigational humanized monoclonal IgG1 antibody that selectively inhibits both IL-17A and IL-17F, two key cytokines driving inflammatory processes.<sup>10</sup> IL-17F has overlapping biology with IL-17A and drives inflammation independently to IL-17A.<sup>11,12,13,14,15</sup> Selective inhibition of IL-17F in addition to IL-17A suppresses inflammation to a greater extent than IL-17A inhibition alone.<sup>14,15</sup> The safety and efficacy of bimekizumab are being evaluated across multiple disease states as part of a robust clinical program.

### **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.

### **Cimzia® (certolizumab pegol) EU/EEA\* Important Safety Information**

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 percent) 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, 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 percent of patients discontinued taking Cimzia® due to adverse events vs. 2.7 percent for placebo.

Cimzia® was initially studied in 325 patients with active axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis) in the AS001 clinical study for up to 4 years, which includes a 24-week placebo-controlled phase followed by a 24-week dose-blind period and a 156-week open-label treatment period. Cimzia® was subsequently studied in 317 patients with non-radiographic axial spondyloarthritis in a placebo-controlled study for 52 weeks (AS0006). Cimzia® was also studied in patients with axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis) in a clinical study for up to 96 weeks, which included a 48-week open-label run-in phase (N=736) followed by a 48-week placebo-controlled phase (N=313) for patients in sustained remission (C-OPTIMISE). In all 3 studies, the safety profile for these patients was consistent with the safety profile in rheumatoid arthritis and previous experience with Cimzia®.

Cimzia® was studied in 409 patients with psoriatic arthritis (PsA) in a clinical study for up to 4 years which included a 24-week placebo-controlled phase followed by a 24-week dose-blind period and a 168-week open-label treatment period.

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 3 years. In the Phase III program, the initial and maintenance periods were followed by a 96-week open-label treatment period. The long-term safety profile of Cimzia® 400 mg every 2 weeks and Cimzia® 200 mg every 2 weeks was generally similar and consistent with previous experience with Cimzia.

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. 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®.

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.

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information.

European SmPC date of revision July 2020.

[https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf)

#### **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 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.

CIMZIA is also indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), adults with active psoriatic arthritis (PsA), adults with active ankylosing spondylitis (AS), and adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

In addition, CIMZIA is indicated for the treatment of moderate to severe plaque psoriasis (PSO) in adults who are candidates for systemic therapy or phototherapy. See important safety information including risk of serious bacterial, viral and fungal infections and tuberculosis below.

#### **IMPORTANT SAFETY INFORMATION about CIMZIA in the U.S.**

##### **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, anaphylaxis, 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, anaphylaxis, 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

[https://www.ucb.com/\\_up/ucb\\_com\\_products/documents/Cimzia\\_09\\_11\\_2019\\_en.pdf](https://www.ucb.com/_up/ucb_com_products/documents/Cimzia_09_11_2019_en.pdf)

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

### **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 7 600 people in approximately 40 countries, the company generated revenue of € 4.9 billion in 2019. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB\_news.

### Forward looking statements UCB

This press release may contain forward-looking statements including, without limitation, statements containing the words “believes”, “anticipates”, “expects”, “intends”, “plans”, “seeks”, “estimates”, “may”, “will”, “continue” and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: the global spread and impact of COVID-19, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, 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, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, 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. There is no guarantee that new product candidates will be discovered or identified in the pipeline, will progress to product approval or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB’s efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB’s products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB’s data and systems.

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<sup>1</sup> Warren R, et al. Bimekizumab efficacy and safety versus adalimumab in patients with moderate to severe plaque psoriasis: Results from a multicentre, randomised, double-blinded active comparator-controlled phase 3 trial (BE SURE). Abstract to be presented at EADV 2020, 29-31 October.

<sup>2</sup> Papp K, et al. Bimekizumab for the treatment of moderate to severe plaque psoriasis with scalp, nail and palmoplantar involvement through 52 weeks: Post-hoc analysis from the BE VIVID phase 3 trial. Abstract to be presented at EADV 2020, 29-31 October.

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<sup>4</sup> Gordon K, et al. Bimekizumab versus ustekinumab in plaque psoriasis: Lasting efficacy translates to rapid and sustained improvements in quality of life in the BE VIVID multicentre, randomised, double-blinded phase 3 trial. Abstract to be presented at EADV 2020, 29-31 October.

<sup>5</sup> Reich K, et al. Bimekizumab safety in patients with moderate to severe psoriasis: Analysis of pooled data from phase 2 and 3 clinical trials. Abstract to be presented at EADV 2020, 29-31 October.

<sup>6</sup> Thaçi D, et al. Long-term improvements in health-related quality of life of patients with moderate to severe plaque psoriasis treated with certolizumab pegol: Results from the CIMPASI-1 and CIMPASI-2 phase 3 trials. Abstract to be presented at EADV 2020, 29-31 October.

<sup>7</sup> European Medicines Agency (EMA). Certolizumab pegol summary of product characteristics, July 2020: [https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf). Last accessed: October 2020.

<sup>8</sup> McBride S, et al. Impact of Psoriatic Disease on Family Planning in Women Aged 18–45: Results from a Multinational Survey across 11 Countries in Europe. Abstract to be presented at EADV 2020, 29-31 October.

<sup>9</sup> Murray S, et al. Psoriasis, pregnancy, and shared decision making: Challenges experienced by dermatologists. Abstract to be presented at EADV 2020, 29-31 October.

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