UCB Showcases Key Rheumatology Data at American College of Rheumatology Convergence 2020

- C-VIEW study results show CIMZIA® (certolizumab pegol) provided reductions in acute anterior uveitis (AAU) flares in patients with axial spondyloarthritis (axSpA)
- C-axSpAnd study shows clinically relevant responses in nr-axSpA patients with either MRI and/or CRP positivity at study baseline
- Long-term findings from Phase 2b studies on UCB's investigational IL-17A and IL-17F inhibitor, bimekizumab, demonstrate consistent durability of clinical responses in patients with ankylosing spondylitis (AS) and psoriatic arthritis (PsA)

Brussels, Belgium – November 5, 2020 – UCB, a global biopharmaceutical company, today announced new data on its TNF inhibitor, CIMZIA® (certolizumab pegol), and investigational IL-17A and IL-17F inhibitor, bimekizumab. Data are being presented at the American College of Rheumatology (ACR) Convergence 2020 virtual congress on November 5-9, 2020.

"The important data we are sharing at ACR Convergence 2020 further highlight UCB's impressive rheumatology research and our unwavering commitment to addressing the unmet needs of patients living with rheumatic diseases. The data demonstrate the real-world difference that CIMZIA can make for axSpA and PsA patients by providing major improvements in disease activity. Our bimekizumab data further support the selective inhibition of IL-17F in addition to IL-17A in AS and PsA, showing that bimekizumab has the potential to provide durable clinical responses impacting overall quality of life," said Emmanuel Caeymaex, Executive Vice President Immunology Solutions and Head of US, UCB.

UCB is sharing two-year data from the Phase 4 C-VIEW study addressing a significant unmet need for axSpA patients with a history of acute anterior uveitis (AAU). AAU is the most common extra-articular manifestation in axSpA, affecting up to 40 percent of patients and causing significant pain and risk of irreversible visual impairment.[1]

The C-VIEW open-label study investigated the impact of CIMZIA treatment on AAU flares in patients with axSpA and a recent history of AAU over a two-year period.[1] The primary efficacy variable was the incidence of AAU flares rate during 96 weeks of CIMZIA treatment versus pre-baseline period.[1] Findings revealed an 82 percent reduction in the incidence of AAU flares during CIMZIA treatment compared to pre-baseline (rate ratio [95 percent CI]: 0.18 [0.12, 0.28], p< 0.001).[1] Improvements in axSpA signs and symptoms were observed by week 96 with 75.6 percent of patients achieving Assessment of SpondyloArthritis international Society 20 (ASAS20) and 58.5 percent achieving ASAS40 responses.[1] No new safety signals were identified, compared to previous reports. [1]

Additionally, UCB is presenting findings from a post hoc analysis of Phase 3 C-axSpAnd study evaluating CIMZIA treatment in patients with non-radiographic axial spondyloarthritis (nr-axSpA).[2] The study identified that patients with nr-axSpA and either evidence at baseline of sacroiliitis on MRI [MRI+] and/or C-reactive protein at least 10mg/ml [CRP+] have clinically relevant responses when treated with CIMZIA over a 52-week period. Relevant responses were measured by percentage of patients achieving major improvement in ASDAS (ASDAS-MI) and ASAS40.[2] Across all three subgroups (MRI+/CRP+, MRI-/CRP+, and MRI+/CRP-), response rates were higher compared to placebo for both ASDAS-MI and ASAS40 at Week 12 and Week 52.[2]

Data presentations from two Phase 2b studies on UCB's investigational IL-17A and IL-17F inhibitor, bimekizumab, highlight rapid clinical improvements in joint and skin outcomes; as well as quality of life measures (QoL) in PsA; and long-term tolerability and consistently durable clinical responses in AS and PsA patients treated with bimekizumab.

- The BE AGILE open-label extension (OLE) study investigated long-term efficacy and safety of bimekizumab treatment in patients with AS over a total treatment duration of 2-years exposure. All patients who entered the OLE trial either continued on 160mg bimekizumab every four weeks (Q4W) or dosed down from 320mg Q4W to 160mg Q4W.[3] Rapid and sustained improvements in all efficacy outcomes observed in patients treated with bimekizumab in the BE AGILE study during weeks 0-48,

were maintained during the OLE from week 48–96 using non-responder imputation methodology.[3] Furthermore, dose reduction at week 48 from 320 mg Q4W to 160 mg Q4W was not followed by loss of response to week 96 and there were no unexpected safety findings versus previous studies.[3]

- The Phase 2b BE ACTIVE study showed that bimekizumab-treated patients with active PsA achieved rapid clinical improvements in joint and skin outcomes as well as improvements in patient-reported quality of life (QoL) measures.[4] Of the patients in the bimekizumab dosing groups (160 mg, 160 mg with a 320 mg loading dose, or 320 mg Q4W), 47.5 to 58.5 percent achieved Health Assessment Questionnaire Disability Index (HAQ-DI) achieving Minimal Clinically Important Difference (MCID), and more than 75 percent achieved Psoriatic Arthritis Impact of Disease-9 (PsAID-9) Patient Acceptable Symptom State (PASS) across weeks 12, 24 and 48, for both measures.[4] These results reinforce bimekizumab's strong potential to positively impact QoL for patients with PsA.[4]
- The BE ACTIVE OLE study investigated long-term efficacy and safety of bimekizumab treatment in patients with active PsA over a total treatment duration of 2-years exposure.[5] All patients who entered the OLE trial received 160 mg Q4W.[5] A high proportion of patients initially randomized to the three highest bimekizumab doses (160 mg, 160 mg with a 320 mg loading dose, or 320 mg Q4W) in the BE ACTIVE study and achieved high levels of disease control at Week 12 demonstrated maintenance of responses for at least 2 years of therapy across both joint and skin outcomes.[5] Rates of treatment-emergent adverse events (TEAEs) occurred in 87.7 percent of patients and serious TEAEs in 9.3 percent of patients. The findings suggest bimekizumab maintains a robust treatment response and high level of disease control up to two years.[5]

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:

Bimekizumab e-Posters:

Bimekizumab Long-Term Efficacy and Safety Over 96 Weeks in Patients with Ankylosing Spondylitis: Interim Results from a Phase 2B Open-Label Extension Study
X Baraliakos, A Deodhar, M Dougados, M Oortgiesen, N de Peyrecave, M Bauer, T Vaux, C Fleurinck, D van der Heijde

Bimekizumab Treatment is Associated with Improvements in Back Pain and Fatigue in Patients with Active Psoriatic Arthritis: 48-Week Results from a Phase 2B Study
A Deodhar, L Gossec, PJ Mease, J Coarse, H Edens, N de Peyrecave, D Assudani, B Ink, CT Ritchlin

Bimekizumab Improves Patient-Reported Outcomes in Psoriatic Arthritis: 48-Week Results from a Phase 2B Study and Association Between Patient-Reported Outcomes and Disease Activity
L Gossec, PJ Mease, AB Gottlieb, D Assudani, J Coarse, B Ink, LC Coates

Bimekizumab Maintenance of Response in Patients with Psoriatic Arthritis: 2-Year Results from a Phase 2B Dose-Ranging Study and its Open-Label Extension
JF Merola, F Behrens, AJ Kivitz, PJ Mease, IB McInnes, B Ink, D Assudani, P Joshi, J Coarse, CT Ritchlin

CIMZIA e-Posters:

Certolizumab Pegol Efficacy in Patients with Non-Radiographic Axial Spondyloarthritis Stratified by Baseline MRI and C-Reactive Protein Status
A Deodhar, LS Gensler, S Hall, PC Robinson, B Hoepken, L Bauer, T Kumke, WP Maksymowych

Predictors of Response in Patients with Non-Radiographic Axial Spondyloarthritis Receiving Certolizumab Pegol in the C-axSpAnd Study
WP Maksymowych, T Kumke, SE Auteri, B Hoepken, L Bauer, M Rudwaleit

Reduction of Anterior Uveitis Flares in Patients with Axial Spondyloarthritis During Certolizumab Pegol Treatment: 96-Week Results from the C-VIEW Study
I van der Horst-Bruinsma, RE van Bentum, FD Verbraak, T Rath, JT Rosenbaum, B Hoepken, O Irvin-Sellers, T Kumke, L Bauer, M Rudwaleit

Network Meta-Analysis of Long-Term Efficacy (ASAS40) of Biologic Disease-Modifying Anti-Rheumatic Drugs (bDMARDs) in bDMARD-Naïve Patients with Non-Radiographic Axial Spondyloarthritis
S Kiri, M Kim, M Betts, M Chitnis, K Fahrbach, J Tarpey, M Turner

Achievement of Remission is Associated with Improvement in Functionality in Certolizumab Pegol-Treated Patients with Psoriatic Arthritis, Irrespective of Pre-Existing Radiographic Structural Damage
LC Coates, D van der Heijde, LE Kristensen, WR Tillett, J Eells, T Nurminen, A Deodhar

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.[6] IL-17F has overlapping biology with IL-17A and drives inflammation independently to IL-17A.[7,8,9,10,11] Selective inhibition of IL-17F in addition to IL-17A suppresses inflammation to a greater extent than IL-17A inhibition alone.[10,11] The safety and efficacy of bimekizumab are being evaluated across multiple disease states as part of a robust clinical program.

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 (≥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

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

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

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 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’ 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.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

UCB is providing this information, including forward-looking statements, only as of the date of this press release and it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated otherwise.

UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. UCB expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

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[1] van der Horst-Bruinsma I, van Bentum RE, Verbraak FD, et al. Reduction of anterior uveitis flares in patients with axial spondyloarthritis during certolizumab pegol treatment: 96-week results from the c-view study. Abstract to be presented at ACR 2020, 5-9 November.

[2] Deodhar A, LS Gensler, Hall S, et al. Certolizumab pegol efficacy in patients with nonradiographic axial spondyloarthritis stratified by baseline mri and creactive protein status. Abstract to be presented at ACR 2020, 5-9 November.

[3] Baraliakos X, Deodhar A, Dougados M, et al. Bimekizumab long-term efficacy and safety over 96 weeks in patients with ankylosing spondylitis: interim results from a phase 2b open-label extension study. Abstract to be presented at ACR 2020, 5-9 November.

[4] Gossec L, Mease PJ, Gottlieb AB, et al. Bimekizumab improves patient-reported outcomes in psoriatic 2 arthritis: 48-week results from a phase 2b study and association 3 between patient-reported outcomes and disease activity. Abstract to be presented at ACR 2020, 5-9 November.

[5] Merola JF, Behrens F, Kivitz AJ, et al. Bimekizumab maintenance of response in patients with psoriatic arthritis: 2 year results from a phase 2b dose ranging study and its open label extension. Abstract to be presented at ACR 2020, 5-9 November.

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[11] 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 randomised placebo-controlled clinical trial that IL-17F contributes to human chronic tissue inflammation. *Ann Rheum Dis*. 2018;77(4):523-532.