

UCB Shares Breadth of Innovative New Data from Rheumatology Portfolio for EULAR 2020 E-Congress

- C-OPTIMISE results give rheumatologists and patients new considerations for the maintenance of remission in axial spondyloarthritis (axSpA) with certolizumab pegol treatment
- Four-year results from the RAPID-axSpA study of CIMZIA® (certolizumab pegol) highlight the importance of early, effective and long-term treatment targeting inflammation
- Robust, patient-reported data on UCB's investigational IL-17A and IL-17F inhibitor, bimekizumab, showcase its potential to make a meaningful difference for people living with ankylosing spondylitis (AS) and psoriatic arthritis (PsA)
- Efficacy and safety of EVENITY®▼ (romosozumab) evaluated among postmenopausal women with osteoporosis and mild-to-moderate chronic kidney disease
- Research unveils barriers to shared decision-making between women with chronic inflammatory diseases and their specialists

Brussels, Belgium – 4 June 2020 – UCB, a global biopharmaceutical company, today announced significant new data on CIMZIA® (certolizumab pegol), EVENITY® (romosozumab) and its investigational IL-17A and IL-17F inhibitor, bimekizumab, that are being presented at the Annual European Congress of Rheumatology (EULAR) 2020. With a total of 14 accepted abstracts and five accepted as oral presentations across multiple rheumatology solutions, UCB's research is set to take center stage at this year's virtual congress.

"We are thrilled to participate in the EULAR 2020 E-Congress and share important information for rheumatologists and their patients. The breadth of data from our rheumatology portfolio shows that we are continuing to connect innovative research to the gaps and barriers in the patient journey, making optimal care possible for more patients every day. With our continued development in axSpA and PsA, and successful launch of EVENITY in osteoporosis, UCB has an incredibly exciting future in rheumatology," said Emmanuel Caeymaex, Executive Vice President Immunology Solutions and Head of US, UCB.

Following are summaries of UCB abstracts accepted as oral presentations.

CERTOLIZUMAB PEGOL C-OPTIMISE STUDY: DOSE REDUCTION FOR MAINTENANCE OF REMISSION IN axSpA

The Phase 3b C-OPTIMISE study of certolizumab pegol is the first-ever randomized, placebo-controlled trial to compare TNF inhibitor full maintenance dose continuation and dose reduction with the effects of treatment withdrawal in patients with axSpA who achieved sustained clinical remission.¹ The findings presented highlight that certolizumab pegol treatment should be continued beyond the achievement of sustained remission. Furthermore, the data confirm that a reduced maintenance dose can be suitable for patients with axSpA who achieve sustained remission following 48 weeks of certolizumab pegol treatment, regardless of axSpA subpopulation (radiographic [r]- and non-radiographic [nr]- axSpA), gender or age.¹ Achievement of a state of low disease activity or remission is key to optimizing health-related quality of life in patients with axSpA. The C-OPTIMISE findings can give rheumatologists and patients an alternative strategy to consider for the maintenance of axSpA remission with certolizumab pegol treatment.

The primary C-OPTIMISE outcome was remaining flare-free during the maintenance period, which was achieved by eight out of ten patients, regardless of whether they took the full certolizumab pegol dose or a reduced maintenance dose.¹ Results showed that 83.7 percent of patients on the full dose (83.9 percent r-axSpA and 83.3 percent nr-axSpA) and 79 percent of those on the reduced maintenance dose (82.1 percent r-axSpA and 75.5 percent nr-axSpA) remained flare-free.¹ Only 20.2 percent of patients randomized to placebo remained flare-free (17.9 percent r-axSpA and 22.9 percent nr-axSpA), underscoring the need for continued treatment after achieving sustained remission.¹ Overall, five serious treatment emergent adverse events (TEAEs) were reported, all of which occurred in patients continuing the full certolizumab pegol maintenance dose.¹ A full recovery was made for all five events, including the two serious TEAEs considered by the study investigator to be treatment-related (one case of intestinal obstruction and one of latent tuberculosis).¹

CIMZIA RAPID-axSpA STUDY: RISK REDUCTION OF SPINAL FAT LESIONS DEVELOPMENT

Four-year results from the RAPID-axSpA study of CIMZIA highlight the importance of early, effective and long-term treatment targeting inflammation.² Spinal fat lesions are one of the tell-tale signs of disease progression, considered to be post-inflammatory precursors to new bone formation that cause worsening of patient mobility and function over time.² RAPID-axSpA results show that reduction of inflammation by week 12 with CIMZIA mitigated the risk of developing fat lesions over four years, while inflammation that prevailed after the start of TNF inhibition treatment was associated with increased fat lesions prevalence over that time.²

CIMZIA C-VIEW STUDY: REDUCTION OF ANTERIOR UVEITIS FLARES IN axSpA

In addition to the above CIMZIA oral presentations, 48-week interim results from the open-label, Phase 4 C-VIEW study of CIMZIA in axSpA will be selected as a poster tour.³ The interim analysis revealed that acute anterior uveitis (AAU) flare rate was significantly reduced in axSpA patients with a history of recurrent AAU during the first 48 weeks of CIMZIA treatment.³ Patients also experienced substantial improvements in axSpA disease activity.³ AAU is reported in up to 40 percent of patients with axSpA, and is associated with significant clinical burden.³ These C-VIEW results provide important information for axSpA patients and their rheumatologists to consider for their treatment plans.

BIMEKIZUMAB BE AGILE STUDY: PATIENT-REPORTED OUTCOMES IN AS

Findings from the Phase 2b BE AGILE study of bimekizumab in ankylosing spondylitis (AS) showed rapid and sustained improvements in patient-reported outcomes with bimekizumab treatment.⁴ Results demonstrated greater improvements at week 12 in spinal pain, fatigue, morning stiffness, sleep, disease activity and quality of life in bimekizumab-treated patients than those receiving placebo.⁴ Responses were further improved and maintained to week 48.⁴ Serious TEAEs occurred in 4.3 percent of patients, which included two major adverse cardiac events considered not related to study drug.⁴ Oral candidiasis occurred in 5.3 percent of patients and did not lead to treatment discontinuation.⁴

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

BARRIERS TO SHARED DECISION-MAKING WITH WOMEN

New survey findings exploring barriers to shared decision-making between patients and their specialists highlight some of the complex reasons why women with chronic inflammatory diseases may be likely to discontinue treatment during pregnancy, as indicated by previous research.⁵

A total of 173 rheumatologists from Germany (G, n=55), the United Kingdom (UK, n=54) and the United States (US, n=64) rated their level of knowledge and skills compared to what is expected in their role.⁵ Respondents scored themselves as sub-optimal against the following key areas relating to the care of women:⁵

- Knowledge of biologic treatments licensed for women of childbearing age (G: 25 percent; UK: 33 percent; US: 22 percent);
- Knowledge of methods to achieve shared decision-making between physicians and patients (G: 34 percent; UK: 40 percent; US: 35 percent);
- Skills discussing contraceptive methods with patients (G: 58 percent; UK: 79 percent; US: 55 percent);
- Skills monitoring changes in pregnancy status or child-bearing aspirations (G: 65 percent; UK: 65 percent; US: 51 percent);
- Skills approaching women of reproductive age in a way that makes them feel comfortable discussing their health concerns (G: 46 percent; UK: 48 percent; US: 44 percent);
 - A greater proportion of male rheumatologists reported having sub-optimal skills in this area, compared to female rheumatologists (52 percent vs 30 percent, p=0.046).

By highlighting the knowledge and skills gaps that prevent optimal shared decision-making, medical learning interventions can be developed to help rheumatologists address the needs of women of childbearing age living with chronic inflammatory diseases.

EVENTITY (ROMOSOZUMAB) IN PATIENTS WITH MILD-TO-MODERATE IMPAIRED RENAL FUNCTION

A post-hoc analysis of the Phase 3 ARCH and FRAME studies evaluated the efficacy and safety of EVENTITY in postmenopausal women with osteoporosis and mild-to-moderate renal insufficiency.⁶

In ARCH, the incidence of new vertebral fractures with EVENTITY versus alendronate at month 12 was – among patients with normal renal function (eGFR \geq 90): 3.3 percent vs 7.3 percent; among patients with mild renal insufficiency (eGFR \geq 60-89): 3.2 percent vs 3.9 percent; and among patients with moderate renal insufficiency (eGFR \geq 30-59): 3.4 percent vs 6.2 percent.⁶

In FRAME, the incidence of new vertebral fractures with EVENTITY versus placebo at month 12 was – among patients with normal renal function (eGFR \geq 90): 0.5 percent vs 3.0 percent; among patients with mild renal insufficiency (eGFR \geq 60-89): 0.4 percent vs 1.5 percent; and among patients with moderate renal insufficiency (eGFR \geq 30-59): 0.6 percent vs 2.1 percent.⁶

In both studies, the incidences of adverse events (AEs) and serious AEs were similar with EVENTITY treatment across different levels of renal function.⁶

Across three different levels of renal function (normal, mild, moderate) EVENTITY treatment resulted in significant bone mineral density gains (from baseline) and a reduction in the risk of new vertebral fractures versus control (alendronate or placebo).⁶

EULAR virtual presentations are available to delegates via the congress portal:

<https://www.congress.eular.org/>.

CIMZIA oral presentations:

Does gender, age or subpopulation influence the maintenance of clinical remission in axial spondyloarthritis following certolizumab pegol dose reduction? R. Landewé, D. van der Heijde, M. Dougados, X. Baraliakos, F. Van den Bosch, K. Gaffney, L. Bauer, B. Hoepken, N. de Peyrecave, K. Thomas, L. Gensler

The impact of persistent inflammatory changes on prevalence of fat lesions in patients with axial spondyloarthritis treated with certolizumab pegol: 4-year MRI results from RAPID-axSpA, X. Baraliakos, S. Kruse, S. Auteri, N. de Peyrecave, T. Nurminen, T. Kumke, B. Hoepken, J. Braun

CIMZIA posters:

Reduction of anterior uveitis flares in patients with axial spondyloarthritis following one year of treatment with certolizumab pegol: 48-week interim results from a 96-week open-label study, I. Van der Horst-Bruinsma, R. Van Bentum, F. Verbraak, T. Rath, J. Rosenbaum, M. Misterska-Skora, B. Hoepken, O. Irvin-Sellers, B. Vanlunen, L. Bauer, M. Rudwaleit

Achievement of very low disease activity and remission treatment targets is associated with reduced radiographic progression in patients with psoriatic arthritis treated with certolizumab pegol, L.C Coates, J.F. Merola, A. Kavanaugh, P.J. Mease, O. Davies, O. Irvin-Sellers, T. Nurminen, D. van der Heijde

Durability of certolizumab pegol in patients with rheumatoid arthritis or psoriasis over three years: an analysis of pooled clinical trial data, V. Bykerk, A. Gottlieb, K. Reich, Y. Tanaka, K. Winthrop, C. Popova, N. Tilt, A. Blauvelt

Certolizumab pegol in patients with rheumatoid arthritis: pooled efficacy analysis of phase 3 clinical trials across baseline rheumatoid factor quartiles, Y. Tanaka, Z. Li, N. Inanc, R. Xavier, N. Tilt, C. Cara, C. Saadoun, T. Takeuchi

Bimekizumab oral presentation:

Efficacy and safety of bimekizumab in ankylosing spondylitis: 48-week patient-reported outcomes from a phase 2b, randomised, double-blind, placebo-controlled, dose-ranging study, D. van der Heijde, L. Gensler, A. Deodhar, X. Baraliakos, D. Poddubnyy, A. Kivitz, M.K. Farmer, D. Baeten, N. Goldammer, J. Coarse, M. Oortgiesen, M. Dougados

Bimekizumab posters and abstracts:

Efficacy and safety of 108 weeks' bimekizumab treatment in patients with psoriatic arthritis: interim results from a phase 2 open-label extension study, I.B. McInnes, J.F. Merola, P.J. Mease, L.C. Coates, P. Joshi, J. Coarse, B. Ink, C.T. Ritchlin

Association between patient-reported outcomes and disease activity in bimekizumab-treated patients with psoriatic arthritis, L. Gossec, P.J. Mease, A. Gottlieb, A. Ogdie, D. Assudani, J. Coarse, B. Ink, L.C. Coates

EVENTITY oral presentation:

Efficacy and safety of romosozumab among postmenopausal women with osteoporosis and mild-to-moderate chronic kidney disease, P. Miller, J. Adachi, B. Albergaria, A. Cheung, A. Chines, E. Gielen, B. Langdahl, A. Miyauchi, M. Oates, I. Reid, N. Ruiz Santiago, M. Vanderkelen, W. Yang, Z. Yu

Shared decision-making oral presentation:

Barriers to shared decision-making with women of reproductive age affected by chronic inflammatory diseases, S. Murray, R. Fischer-Betz, M. Augustyniak, J. Murase, C. Nelson-Piercy, I. Vlaev, C. Ecoffet, M. Peniuta, D. Jenkins

Other UCB abstracts:

Awareness about family planning and pregnancy expectation among patients with chronic inflammatory disease of the skin or joints, K. Schreiber, C. Johansen, U. Jensen, A. Egeberg, S. Thomsen, A. Hansen, T. Laurberg, L. Skov, L. Kristensen

Tumour necrosis factor inhibitor therapy does not reduce the incidence of comorbidities and extra-articular manifestations in ankylosing spondylitis: an analysis of three US claims databases, A. Deodhar, K. Winthrop, R. Bohn, B. Chan, R. Suruki, J. Stark, H. Yun, S. Siegel, L. Chen, J. Curtis

Annual diagnostic prevalence of ankylosing spondylitis (AS) in the United States using Medicare and MarketScan data, J. Curtis, K. Winthrop, B. Chan, S. Siegel, J. Stark, R. Suruki, R. Bohn, F. Xie, H. Yun, L. Chen, A. Deodhar

About CIMZIA® in the EU/EEA

In the EU, CIMZIA® in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active RA in adult patients inadequately responsive to disease-modifying anti-rheumatic drugs (DMARDs) including MTX.

CIMZIA can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. CIMZIA in combination with MTX is also indicated for the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs.

CIMZIA has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX.

CIMZIA, in combination with MTX, is also indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. CIMZIA can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

CIMZIA is also indicated in the EU for the treatment of adult patients with severe active axial spondyloarthritis (axSpA), comprising:

- Ankylosing spondylitis (AS) – adults with severe active AS who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).
- Axial spondyloarthritis (axSpA) without radiographic evidence of AS – adults with severe active axSpA without radiographic evidence of AS but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or Magnetic Resonance Imaging (MRI) who have had an inadequate response to, or are intolerant to NSAIDs.

CIMZIA is also indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

About CIMZIA® in Fertility, Pregnancy and Lactation in the EU/EEA

Women of childbearing potential

The use of adequate contraception should be considered for women of childbearing potential. For women planning pregnancy, continued contraception may be considered for 5 months after the last CIMZIA® dose due to its elimination rate, but the need for treatment of the woman should also be taken into account (see below).

Pregnancy

Data from more than 500 prospectively collected pregnancies exposed to CIMZIA with known pregnancy outcomes, including more than 400 pregnancies exposed during the first trimester, does not indicate a malformative effect of CIMZIA. However, the available clinical experience is too limited to, with a reasonable certainty, conclude that there is no increased risk associated with CIMZIA administration during pregnancy.

Animal studies using a rodent anti-rat TNF α did not reveal evidence of impaired fertility or harm to the foetus. However, these are insufficient with respect to human reproductive toxicity. Due to its inhibition of TNF α , CIMZIA administered during pregnancy could affect normal immune response in the newborn.

CIMZIA should only be used during pregnancy if clinically needed. Pharmacokinetic studies suggest low or negligible level of placental transfer of a homologue Fab-fragment of certolizumab pegol (no Fc region).

In a clinical study 16 women were treated with certolizumab pegol (200 mg every 2 weeks or 400 mg every 4 weeks) during pregnancy. Certolizumab pegol plasma concentrations measured in 14 infants at birth were Below the Limit of Quantification (BLQ) in 13 samples; one was 0.042 μ g/ml with an infant/mother plasma ratio at birth of 0.09 percent. 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 percent to 0.30 percent. 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.

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 studied in 325 patients with active axial spondyloarthritis (axSpA) 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 156-week open-label treatment period and in 317 patients with non-radiographic axial spondyloarthritis in a placebo-controlled study for 52 weeks (AS0006).

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 GL-P-CZ-axSpA-1900034 Important Safety Information Cimzia Revised April 2020 * EU/EEA means European Union/European Economic Area clinical symptoms and/or radiographic evidence of demyelinating disease including multiple sclerosis; of formation of autoantibodies and uncommonly of the development of a lupuslike 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 April 2020.

https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-productinformation_en.pdf

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

About Bimekizumab

Bimekizumab is an investigational humanized monoclonal IgG1 antibody that selectively inhibits both IL-17A and IL-17F, two key cytokines that drive inflammation and tissue damage across multiple diseases.⁷ IL-17F has overlapping biology with IL-17A and can drive inflammation independently to IL-17A.^{8,9,10,11,12} Selective inhibition of IL-17F in addition to IL-17A suppresses inflammation to a greater extent than IL-17A inhibition alone.^{11,12} The safety and efficacy of bimekizumab are being evaluated across multiple disease states as part of a robust clinical program. UCB plans to submit applications to regulatory authorities for approval of bimekizumab to treat adults with moderate-to-severe plaque psoriasis in 2020.

About EVENITY® (romosozumab)

Romosozumab is a bone-forming monoclonal antibody.¹³ It is designed to work by inhibiting the activity of sclerostin, which simultaneously results in increased bone formation and to a lesser extent decreased bone resorption.¹³ The romosozumab development program includes 19 clinical studies that enrolled approximately 14,000 patients.¹⁴ Romosozumab has been studied for its potential to reduce the risk of fractures in an extensive global Phase 3 program that included two large fracture trials comparing romosozumab to either placebo or active comparator in over 11,000 postmenopausal women with osteoporosis.^{15,16} Amgen and UCB are co-developing romosozumab.

Important Safety Information about EVENITY® (romosozumab)

In the EU, Romosozumab is indicated for treatment of severe osteoporosis in postmenopausal women at high risk of fracture. **Contraindications:** Romosozumab is contraindicated in patients who are allergic to romosozumab or any of the excipients, who have low levels of calcium in the blood (hypocalcaemia), or who have a history of myocardial infarction (heart attack) or stroke. **Myocardial infarction or stroke:** Heart attack and stroke have been reported in patients receiving Romosozumab in randomised controlled trials (uncommon). Treatment with Romosozumab should not be initiated in patients with a history of heart attack or stroke. When determining whether to use Romosozumab for an individual patient, the presence of risk factors for cardiovascular problems, including established cardiovascular disease, high blood pressure, high blood fat levels, diabetes, smoking or kidney problems, should be evaluated. Romosozumab should only be used if the prescriber and patient agree that the benefit outweighs the risk. If a patient experiences a myocardial infarction or stroke during therapy, treatment with Romosozumab should be discontinued. **Hypocalcaemia:** Transient hypocalcaemia has been observed in patients receiving Romosozumab. Hypocalcaemia should be corrected prior to initiating therapy with Romosozumab and patients should be monitored for signs and symptoms of hypocalcaemia. If any patient presents with suspected symptoms of hypocalcaemia during treatment, calcium levels should be measured. Patients should be adequately supplemented with calcium and vitamin D. Patients with severe renal impairment (estimated glomerular filtration rate [eGFR] 15 to 29ml/min/1.73m²) or receiving

dialysis are at greater risk of developing hypocalcaemia and the safety data for these patients are limited. Calcium levels should be monitored in these patients. **Hypersensitivity:** Clinically significant hypersensitivity reactions, including angioedema, erythema multiforme, and urticaria occurred in the Romosozumab group in clinical trials. If an anaphylactic or other clinically significant allergic reaction occurs, appropriate therapy should be initiated and use of Romosozumab should be discontinued. **Osteonecrosis of the Jaw:** Osteonecrosis of the jaw (ONJ) has been reported rarely in patients receiving Romosozumab. The following risk factors should be considered when evaluating a patient's risk of developing ONJ: (1) potency of the medicinal product that inhibits bone resorption (the risk increases with the antiresorptive potency of the compound), and cumulative dose of bone resorption therapy, (2) cancer, co-morbid conditions (e.g. anaemia, coagulopathies, infection), smoking, (3) concomitant therapies: corticosteroids, chemotherapy, angiogenesis inhibitors, radiotherapy to head and neck, (4) poor oral hygiene, periodontal disease, poorly fitting dentures, history of dental disease, invasive dental procedures e.g. tooth extractions. All patients should be encouraged to maintain good oral hygiene and receive routine dental check-ups. Dentures should fit correctly. Patients under dental treatment, or who will undergo dental surgery (e.g. tooth extractions) whilst being treated with Romosozumab should inform their doctor about their dental treatment and inform their dentist that they are receiving Romosozumab. Patients should immediately report any oral symptoms such as dental mobility, pain or swelling or non-healing of sores or pus discharge during treatment with Romosozumab. Patients who are suspected of having or who develop ONJ while receiving Romosozumab should receive care by a dentist or an oral surgeon with expertise in ONJ. Discontinuation of Romosozumab therapy should be considered until the condition resolves and contributing risk factors are mitigated where possible. **Atypical Femoral Fractures:** Atypical low-energy or low trauma fracture of the femoral shaft, which can occur spontaneously, has been reported rarely in patients receiving Romosozumab. Any patient who presents with new or unusual thigh, hip, or groin pain should be suspected of having an atypical fracture and should be evaluated to rule out an incomplete femur fracture. Patient presenting with an atypical femur fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of Romosozumab therapy should be considered, based on an individual benefit-risk assessment. **Adverse Reactions:** The most common adverse reactions were nasopharyngitis (13.6 percent) and arthralgia (12.4 percent). Common adverse reactions included hypersensitivity, sinusitis, rash, dermatitis, headache, neck pain, muscle spasms and injection site reactions (most frequent injection site reactions were pain and erythema). Uncommon adverse reactions were urticaria, hypocalcaemia, stroke, myocardial infarction and cataract. Finally, rare side effects were serious allergic reactions which caused swelling of the face, throat, hands, feet, ankles or lower legs (angioedema) and acute skin eruption (erythema multiforme).

Refer to the attached [European Summary of Product Characteristics](#) for other adverse reactions and full prescribing information for EVENITY® ▼.

▼ This medicinal product is subject to additional monitoring.

About the Amgen and UCB Collaboration

Since 2004, Amgen and UCB have been working together under a collaboration and license agreement to research, develop and market antibody products targeting the protein sclerostin. As part of this agreement, the two companies continue to collaborate on the development of romosozumab for the treatment of osteoporosis. This gene-to-drug project demonstrates how Amgen and UCB are joining forces to translate a genetic discovery into a new medicine, turning conceptual science into a reality.

CONTACT: UCB, Brussels

Scott Fleming, Bone Communications, UCB, T +44 7702777378, scott.fleming@ucb.com
Laurent Schots, Media Relations, UCB, T+32.2.559.92.64, laurent.schots@ucb.com
Antje Witte, Investor Relations, UCB, T +32.2.559.94.14, antje.witte@ucb.com
Isabelle Ghellynck, Investor Relations, UCB, T+32.2.559.9588, isabelle.ghellynck@ucb.com

CONTACT: Amgen, Thousand Oaks

Jessica Akopyan, 805-447-0974 (media)
Trish Hawkins, 805-447-5631 (media)
Arvind Sood, 805-447-1060 (investors)

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

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For further information, UCB:

Corporate Communications
Laurent Schots,
Media Relations, UCB

T+32.2.559.92.64,
laurent.schots@ucb.com

Investor Relations
Antje Witte,
Investor Relations, UCB

T +32.2.559.94.14,
antje.witte@ucb.com

Investor Relations
Isabelle Ghellynck,
Investor Relations, UCB

T+32.2.559.9588,
isabelle.ghellynck@ucb.com

Brand Communications
Andrea Christopher,
Immunology Communications, UCB

T +1.404.483.7329
andrea.christopher@ucb.com

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