UCB News

Latest real-world evidence presented at WCO-IOF-ESCEO assesses how EVENITY® ▼ (romosozumab) can help to close the treatment gap in osteoporosis

- The first cohort patient study in Denmark for romosozumab highlights its use in routine clinical practice.
- Patients within the romosozumab cohort group had a fracture history in the past three years which included hip and spine fractures prior to treatment with romosozumab.[1]
- The study observations can help to inform optimal clinical use of romosozumab for postmenopausal women at high risk of fracture.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Brussels (Belgium), 12 April 2024 – UCB, a global biopharmaceutical company, today announced key findings from the first retrospective patient cohort study in Denmark to observe the characteristics of patients selected for romosozumab treatment in routine clinical practice. The data were presented as a poster presentation at the World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (WCO-IOF-ESCEO) 2024 in London, UK, 11-14 April.

The observational, retrospective cohort study included female patients aged 50 years or older receiving osteoporosis medication during September 2020 to October 2023, identified by prescription and hospital registry data. Overall, 149,395 patients were included in the analysis; of these, 622 with a fracture in the three years before the date of cohort entry were treated with romsozumab.[1]

The study observed that, of patients who had sustained a fracture at any skeletal site in the three years before the date of cohort entry and were treated with romosozumab, fracture history included hip fractures (n=79/N=622 (12.7%)) and spine fractures (n=64/N=622 (10.3%)), in addition to non-hip, non-spine (n=303/N=622 (48.7%)) and osteoporosis with pathological fracture not related to malignancy or other bone diseases (n=335/N=622 (53.9%)). The study also highlighted that of the 622 female patients treated with romosozumab, 44.5% (n=277) had not received any prior treatment for osteoporosis.[1]

"It is vital that patients with osteoporosis at high risk of fracture receive timely and appropriate care from the offset to reduce the risk of future fractures and improve outcomes," said lead study investigator Prof Bente Langdahl (Clinical Professor, Aarhus University Hospital, Denmark). "By offering critical insights into the treatment patterns of romosozumab and other osteoporosis treatments in a real-world setting, this study allows us to further investigate prescription patterns and the profile of patients who may benefit the most

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from the use of romosozumab as a first-line treatment. This knowledge will help us improve treatment of patients with severe osteoporosis at high risk of fracture."

The global impact of osteoporosis is profound, with one in three women over the age of 50 likely to experience a fracture caused by osteoporosis.[2] In Europe alone, the economic cost is estimated at 37.5 billion EUR – a number predicted to increase by 27% by 2030.[3] Despite this, data in Europe has demonstrated that up to 85% of women are not treated for underlying osteoporosis following a fragility fracture.[4]

"This cohort patient study provides an invaluable blueprint to inform future treatment decision-making and support optimal use of romosozumab in clinical practice, both in Denmark and across Europe," said Emmanuel Caeymaex, Executive Vice President, Immunology and U.S. Solutions at UCB. "The study findings enable us to understand the use of romosozumab as a treatment option in the real world and demonstrate its potential in closing the treatment gap for patients at high risk of fracture."

Romosozumab was approved in the European Union in December 2019 for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture.[5]

WCO - World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases; IOF - International Osteoporosis Foundation, ESCEO - European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis.

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About the European retrospective cohort study

A retrospective cohort study was conducted using data recorded from Danish administrative registries. The study population comprised female patients aged ≥50 receiving osteoporosis medication during the period from September 2020 to October 2023. The objective of the study is to observe patterns and influencing factors of romosozumab use in routine clinical practice in Denmark. The study included three cohorts: i) patients with severe osteoporosis treated with romosozumab, ii) patients with severe osteoporosis not treated with romosozumab, and iii) patients who did not have severe osteoporosis and were not treated with romosozumab. Patients were considered as having severe osteoporosis if they had sustained a fracture at any skeletal site in the three years before the index date (BMD data were not available in the dataset). The characteristics investigated in the three cohorts included: age, index treatment, comorbidities, osteoporosis treatment history, dispensing of drugs that increase risk of falling and fracture, fracture history, and use of glucocorticoids.

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About EVENITY® (romosozumab)

Romosozumab is a bone-forming monoclonal antibody. 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. The romosozumab development program includes 19 clinical studies that enrolled approximately 14,000 patients. EVENITY 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. Amgen and UCB are co-developing romosozumab.

Important Safety Information about EVENITY® (romosozumab) in the EU/EEA

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%) and arthralgia (12.4%). 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 European Summary of Product Characteristics for other adverse reactions and full prescribing information. Available at https://www.ema.europa.eu/en/documents/product-information/evenity-epar-product-information_en.pdf.

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 8,000 people operating in more than 40 countries, the company generated revenue of €5.3 billion in 2020. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

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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.

Forward looking statements

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees.

UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations. There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.

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