UCB News

Global data show real-world effectiveness of romosozumab for patients at high fracture risk

- A systematic literature review across 10 countries showed that romosozumab improved bone mineral density with larger gains than comparators at 12 months.[1]
- A retrospective claims analysis on healthcare resource utilization in romosozumab treatment in Germany showed patient cost reduction during the second year after initial administration.[2]
- UCB has presented four abstracts at WCO-IOF-ESCEO 2025, further demonstrating the real-world evidence of romosozumab.

Brussels (Belgium), April 11, 2025 – 14:00 (CET) – UCB, a global biopharmaceutical company, today announced findings from a collection of real-world evidence studies to reaffirm the effectiveness and clinical impact of romosozumab, the only dual-acting osteoporosis treatment that increases bone formation and decreases bone resorption, around the world.[3] The data were presented as a poster at the 25th World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (WCO-IOF-ESCEO) 2025 in Rome, Italy, 10-13 April.

A systematic literature review identified 362 records from 67 studies across 10 countries and found that romosozumab was associated with significant improvements in bone mineral density (BMD) at 12 months versus baseline in lumbar spine, total hip and femoral neck studies. BMD gains in treatment-naïve patients were significantly larger compared with previously treated patients, emphasizing the importance of treatment sequencing.[1]

"This collection of evidence across multiple countries further confirms that treating patients at high fracture risk with romosozumab at the right time plays a crucial role in strengthening bones and significantly reducing fracture risk," said lead study investigator Prof Bente Langdahl (Clinical Professor, Aarhus University Hospital, Denmark). "By following the established guidelines that advise optimal treatment sequencing, healthcare professionals have the potential to change the trajectory of a patient's fracture risk."

At WCO-IOF-ESCEO 2025, UCB is further expanding the real-world evidence base for romosozumab with multiple data readouts:

- A retrospective analysis of healthcare resource utilization in Germany found that total patient costs the year before (11,109 EUR [SD 13,314; median 8,033]) and the year after starting romosozumab (18,630 EUR [SD 24,470; median 12,215] were similar despite the additional cost

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of the medication. Costs decreased below pre-treatment levels in the second year (5,604 EUR [SD 7,778], indicating potential long-term cost-effectiveness and reduced healthcare burden.[2]

- In a Swedish registry study on osteoporosis, over three-quarters of patients (76.9%) treated with romosozumab were treatment-naïve, indicating broad adoption of osteoanabolic therapy as a first-line approach.[4]
- A claims data analysis on women aged 55+ in Germany found gaps in osteoporosis guideline-adherent treatment, with many women with high-risk fractures remaining untreated, leading to more secondary fractures. This highlights the urgent need for adherence to the 2023 Guideline of the Dachverband Osteologie for the Prevention, Diagnosis and Therapy of Osteoporosis in Adults (DVO) guideline, which includes a 3-year fracture risk threshold for timely treatment.[5]

"We have the opportunity to make this a defining era in osteoporosis management, where no woman at high risk of fracture is overlooked or untreated," said Emmanuel Caeymaex, Chief Commercial Officer and Head of Patient Impact, UCB. "The growing body of real-world evidence behind romosozumab reinforces our continued commitment of bringing meaningful benefits to patients and provides healthcare professionals with the confidence that romosozumab will deliver significant improvements in the clinical setting."

Romosozumab was approved in the European Union in December 2019 for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture.[3]

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Notes to editors:

About the real-world effectiveness of romosozumab: a systematic literature review
A systematic literature review (SLR) was conducted according to Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. MEDLINE, Embase and relevant conference proceedings were searched to 2nd December 2024 for observational studies of patients receiving romosozumab reporting effectiveness outcomes.

The SLR identified 362 records, of which 67 unique studies across 10 countries were included. The majority were retrospective cohort studies (n=39) and 29/67 were comparative. Numbers of patients ranged from six to 29,512 for romosozumab and 21 to 537,927 for comparators, with denosumab most commonly reported. Mean patient age ranged from 52.3 to 84.4 years.

Across both romosozumab and comparator arms, mean bone mineral density (BMD; T-score) at baseline ranged from –3.80 to –1.79 at the lumbar spine, –3.00 to –2.15 at the total hip, and –3.30 to –2.20 at the femoral neck. Mean percentage change in lumbar spine BMD at 12 months ranged from 0.97% to 20.0% and 1.07% to 8.10% for patients treated with romosozumab and comparators, respectively. Mean percentage change in total hip BMD ranged from –0.40% to 9.10% (romosozumab) and –2.80% to 3.60% (comparators) with similar changes in femoral neck BMD.[1]

About the claims data analysis on women aged 55+ in Germany

This retrospective analysis of a German claims database (4.1 million insured) included statutorily health insured (SHI) women aged 55+ years with proximal femoral or vertebral fractures in 2017–2021. In untreated femoral fracture patients (n=282,026; period 2017–2021), 28.1% had another femoral fracture and 5.0% a vertebral fracture within one year. Untreated patients with vertebral fracture (n=630,102) had a risk of 27.8% for a second vertebral and 2.0% for a femoral fracture within one year after index.[5]

About 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. 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. Amgen and UCB are co-developing romosozumab.

Important Safety Information about 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

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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

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. UCB has rights to lead commercialization for EVENITY in most countries in Europe. Amgen, as the principal, leads commercialization for EVENITY and recognizes product sales in all other territories, including the United States. 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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