UCB News

UCB highlights latest EVENITY™ (romosozumab) research at the American Society for Bone and Mineral Research Annual Meeting

- **First presentation of romosozumab ARCH study results and FRAME extension study**

BRUSSELS, BELGIUM (Sept. 8th, 2017) – UCB (Euronext Brussels: UCB) today announced that eight scientific abstracts will be presented at this year's Annual Meeting of the American Society for Bone and Mineral Research (ASBMR) in Denver, Colorado, from September 8-11, 2017. These abstracts will highlight some of the latest scientific research on post-fracture management and EVENITY™* (romosozumab).

The ASBMR congress will feature the first presentation of detailed results from the romosozumab Phase 3 active-comparator ARCH study. In addition, two abstracts from the romosozumab Phase 3 placebo-controlled FRAME study of more than 7,000 postmenopausal women with osteoporosis will be presented, as well as two abstracts exploring the effects of romosozumab on bone tissue in postmenopausal women with osteoporosis after 2 and 12 months of treatment.

"Worldwide, one fragility fracture occurs approximately every 3 seconds, and can lead to chronic pain, premature mortality, permanent disability and loss of independence. Improving the care of fragility fracture sufferers and eliminating the secondary prevention care gap has driven our research over the last decade and this is reflected in the data being presented at ASBMR 2017," commented Dr. Pascale Richetta, Head of Bone and Executive Vice President at UCB. "At this year's congress we are pleased, along with our partner Amgen, to share with the scientific community the latest romosozumab clinical findings as we continue to help advance scientific understanding and address the crisis in fragility fracture management."

Romosozumab is an investigational bone-forming monoclonal antibody designed to inhibit the protein sclerostin. It has an overall dual effect on bone, increasing bone formation and decreasing bone resorption.

Romosozumab is being co-developed by Amgen and UCB.

ABSTRACTS OF INTEREST

Romosozumab

- **A Randomized Alendronate Controlled Trial of Romosozumab: Results of the Phase 3 ARCH Study (Active-controlled fracture study in postmenopausal women with osteoporosis at high risk) -** Abstract LB-1162, Oral Presentation, Monday, Sept. 11, 11:45-11:55a.m. MT (Mile High Ballroom)
- **Continued Fracture Risk Reduction After 12 Months of Romosozumab Followed by Denosumab Through 36 Months in the Phase 3 FRAME (Fracture study in postmenopausal women with osteoporosis) Extension -** Abstract 1071, Oral Presentation, Sunday, Sept. 10, 9:45-10:00a.m. MT (Mile High Ballroom)
- **FRAME Study: The Foundation Effect of Rebuilding Bone With One Year of Romosozumab Leads to Continued Lower Fracture Risk After Transition to Denosumab -** Abstract 1110, Oral Presentation, Sunday, Sept. 10, 4:30-4:45p.m. MT (Mile High Ballroom)

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* The trade name EVENITY™ is provisionally approved for use by the U.S. Food and Drug Administration and the European Medicines Agency

- **Effects of Romosozumab in Postmenopausal Women With Osteoporosis After 2 and 12 Months: Bone Histomorphometry Substudy -** Abstract 1072, Oral Presentation, Sunday, Sept. 10, 10:00-10:15a.m. MT (Mile High Ballroom)
- **Effects of Romosozumab in Postmenopausal Women With Osteoporosis After 2 and 12 Months Assessed by MicroCT on Iliac Crest Bone Biopsies -** Abstract MO0128, Poster Presentation, Monday, Sept. 11, 12:00.-2:00p.m. MT (ASBMR Discovery Hall)

Disease-state

- **Predictors of Near-Term Non-Vertebral Fracture in Elderly Women with Osteoporosis, Osteopenia, or a History of Fracture, Based on Data from the Canadian Multicentre Osteoporosis Study (CaMos) -** Abstract FR0264 and SA0264, Plenary Poster, Friday, Sept. 8, 5:00-7:00p.m. MT and Saturday, Sept. 9, 12:30 p.m.-2:30 p.m. MT (ASBMR Discovery Hall – Exhibit Hall A)
- **Changes in Bone Mineral Density (BMD): A Longitudinal Study of Osteoporosis Patients -** Abstract SA0072, Poster Presentation, Saturday, Sept. 9, 12:30-2:30p.m. MT (ASBMR Discovery Hall – Exhibit Hall A)
- **Testing an Evidence-based Theoretical Model of Imminent (1-year) Fracture Risk in Elderly Women: Results from the Canadian Multicentre Osteoporosis Study (CaMOS) -** Abstract SU0316, Poster Presentation, Sunday, Sept. 10, 12:30-2:30p.m. MT (ASBMR Discovery Hall – Exhibit Hall A)

About EVENITY

EVENITY is an investigational bone-forming monoclonal antibody and is not approved by any regulatory authority for the treatment of osteoporosis. It is designed to work by inhibiting the activity of sclerostin and has a dual effect on bone, increasing bone formation and decreasing bone resorption. EVENITY is being studied for its potential to reduce the risk of fractures in an extensive global Phase 3 program. This program includes two large fracture trials comparing EVENITY to either placebo or active comparator in more than 10,000 postmenopausal women with osteoporosis. Amgen and UCB are co-developing EVENITY.

About the ARCH study

ARCH (Active-contRolled FraCture Study in Postmenopausal Women with Osteoporosis at High Risk of Fracture) is a Phase 3 multicenter, international, randomized, double-blind, alendronate-controlled study of EVENITY in postmenopausal women with osteoporosis at high risk for fracture based on previous fracture history. The study evaluated 12 months of EVENITY treatment followed by at least 12 months of alendronate treatment, compared with alendronate treatment alone. The purpose of this study was to determine if EVENITY treatment is effective in reducing the incidence of clinical fracture (non-vertebral fracture and clinical vertebral fracture) and new vertebral fracture. The incidence of clinical fracture was event-driven and the primary analysis occurred when 330 fractures occurred or the last patient was on the study for 24 months, whichever was later.

Patients (4,093) were randomized 1:1 to receive either 210 mg EVENITY subcutaneously every month or 70 mg alendronate orally every week for the duration of the 12-month double-blind alendronate-controlled study period. After the double-blind active-comparator study period, patients received alendronate while remaining blinded to their initial treatment assignment.

About the FRAME study

FRAME (FRActure study in postmenopausal woMen with ostEoporosis) is a multicenter, international, randomized, double-blind, placebo-controlled, parallel-group study in postmenopausal women with osteoporosis, defined as low bone mineral density at the total hip or femoral neck. The study evaluated the effectiveness of romosozumab treatment, compared with placebo, in reducing the risk of new vertebral fractures through 12 months. The study also further evaluated if romosozumab treatment for 12 months followed by denosumab treatment for 12 months, compared with placebo followed by denosumab treatment, was effective in reducing the risk of new vertebral fractures through 24 months. In addition, clinical fracture (a composite endpoint which encompasses all symptomatic fractures, both non-vertebral and painful vertebral fractures) risk reduction, non-vertebral fracture (fractures outside of the spine, excluding sites that are not considered osteoporotic, fractures due to high trauma or pathologic fractures) risk reduction and other endpoints were assessed at 12 and 24 months.

7,180 patients were randomized 1:1 to receive either 210 mg romosozumab subcutaneous (SC) monthly (QM) or placebo SC QM for the 12-month double-blind study period. After the placebo-controlled study period, patients entered the open-label phase where all patients received 60 mg denosumab SC every six months (Q6M) for 12 months, while remaining blinded to initial treatment. An additional 12 month extension period of open-label 60 mg denosumab SC Q6M is currently ongoing.

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 7,500 people in approximately 40 countries, the company generated revenue of € 4.2 billion in 2016. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

UCB 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.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction. UCB is providing this information as of the date of this presentation 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.

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 EVENITY 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.

For further information

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