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UCB to present pivotal FRAME data at #ASBMR16

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UCB
News

UCB to present results from Phase 3 FRAME Study at the American Society for Bone and Mineral Research (ASBMR) Annual Meeting

- **FRAME evaluated the efficacy and safety of romosozumab treatment in postmenopausal women with osteoporosis**
- **FRAME abstract receives the 2016 ASBMR Most Outstanding Clinical Abstract Award**
- **Robust suite of additional presentations reinforces understanding of osteoporosis and fracture risk**

Brussels, Belgium, 7th September, 2016, 07:00 – UCB (Euronext Brussels: UCB) and Amgen (NASDAQ: AMGN) today announced that they are presenting Phase 3 data for the investigational agent romosozumab at the annual meeting of the American Society for Bone and Mineral Research (ASBMR) in Atlanta on Sept. 16-19, 2016. At the congress, additional presentations will also highlight data providing key insights around the long-term burden of fractures and research related to identifying patients at increased risk of fracture.

“We look forward to presenting detailed data from the Phase 3 FRAME study of romosozumab at ASBMR which provide further understanding of the potential role of romosozumab in reducing the risk of fragility fractures,” said Dr Pascale Richetta, Head of Bone and Executive Vice President at UCB. *“Fragility fractures are often the first sign of osteoporosis, a disease that remains underdiagnosed and undertreated. In addition, a fracture identifies a patient at high risk of a subsequent fracture and so should signal the need for physician intervention with the aim of helping patients live free from the worry of the next fracture.”*

The romosozumab FRAME abstract, “Fracture Risk Reduction With Romosozumab: Results of the Phase 3 FRAME Study (FRActure study in postmenopausal woMen with ostEoporosis)” has been awarded the 2016 ASBMR Most Outstanding Clinical Abstract Award, which is selected by the ASBMR scientific committee and given to the lead investigator. Lead author Dr. Felicia Cosman, Medical Director of the Clinical Research Center at Helen Hayes Hospital, Professor of Medicine at Columbia University College of Physicians and Surgeons in New York, will be presented with the award on Sunday, September 18.

UCB and Amgen submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for romosozumab in July 2016. Romosozumab is being co-developed by UCB and Amgen.

The following is a guide to the UCB/Amgen sponsored data presentations.

Romosozumab Oral Presentations

- **Fracture Risk Reduction With Romosozumab: Results of the Phase 3 FRAME Study (FRActure study in postmenopausal woMen with ostEoporosis).** Abstract 1096, Oral Presentation, [Sunday], September 18, 09:45. ET
- **Effects of Romosozumab on Remodeling and Bone Strength at the Distal Radius in Ovariectomized Cynomolgus Monkeys.** Abstract 1024, Oral Presentation, [Friday] September 16, 15:45. ET

Romosozumab Abstracts of Interest

- **Romosozumab Blocks the Binding of Sclerostin to the Two Key Wnt Signaling Co-receptors, LRP5 and LRP6, but not to LRP4.** Abstract MO0300, Poster Presentation, [Monday], September 19, 12:30-14:30. ET

Osteoporosis Abstracts of Interest

- **Estimating the Long-Term Functional Burden of Osteoporosis-Related Fractures,** Abstract MO0243, Poster Presentation, [Monday], September 19, 12:30-14:30 ET
- **High Risk of Second Fracture within 1, 2, 5 years after Prior Fracture among Women 65 years or Older,** Abstract FR0233, Poster Presentations, [Friday] September 16, 17:30-19:00 ET and Abstract SA0233, Poster Presentation, [Saturday] September 17, 12:30-14:30 ET
- **Prediction of two-year risk of fracture among older US women,** Abstract FR0237, Poster Presentations, [Friday] September 16, 17:30-19:00 ET and Abstract SA0237, Poster Presentation, [Saturday] September 17, 12:30-14:30 ET
- **Predictors of Imminent Risk of Non-Vertebral Fracture in Older Women: The Framingham Osteoporosis Study,** Abstract MO0232, Poster Presentation, [Monday], September 19, 12:30-14:30 ET
- **Predictors of Imminent Fracture Risk in Medicare-enrolled Men and Women,** Abstract SU0227, Poster Presentation, [Sunday], September 18, 12:30-14:30 ET
- **Characteristics of Patients at High One-year Fracture Risk,** Abstract MO0223, [Monday], September 19, 12:30-14:30 ET

About Romosozumab

Romosozumab is an investigational bone-forming agent and is not approved by any regulatory authority for the treatment of osteoporosis. It is designed to work by inhibiting the protein sclerostin, thereby increasing bone formation and decreasing bone breakdown. Romosozumab 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 romosozumab to either placebo or active comparator in more than 10,000 patients with osteoporosis. Romosozumab is being co-developed by UCB and Amgen.

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 7,700 people in approximately 40 countries, the company generated revenue of € 3.9 billion in 2015. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

About the UCB and Amgen 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 sclerostin protein. 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 turn genetic discoveries into new medicine, turning conceptual science into a reality.

Forward looking statements – UCB

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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