UCB News

UCB Highlights Data to Be Presented At American Society for Bone and Mineral Research 2018 Annual Meeting

- **New ARCH Trial data analysis shows T-score as Indicator of Fracture Risk on Therapy: Evidence From Active Comparator Study of EVENITY™ (Romosozumab) in Post-Menopausal Women With Osteoporosis**

BRUSSELS, BELGIUM (Sept. 25th, 2018) – UCB (Euronext Brussels: UCB) today announced that the latest observations from the EVENITY™* (romosozumab) clinical data and findings from collaborative studies that advance knowledge on the treatment gap and sclerostin biology, will be presented at the Annual Meeting of the American Society for Bone and Mineral Research (ASBMR) in Montreal, Quebec, Canada from September 28 – October 1, 2018. Romosozumab, is an investigational bone-forming monoclonal antibody that increases bone formation and reduces bone resorption to increase bone mineral density (BMD) and reduce the risk of fracture.

“We believe the new data analyses from the Phase 3 active-comparator ARCH study, and additional research on fragility fracture diagnosis, management and prevention, will be valuable to our ongoing goal of improving care and treatment options of those impacted by fragility fractures,” said Dr. Pascale Richetta, Head of Bone and Executive Vice President at UCB. “It is estimated that nearly 80 percent of individuals who have already had at least one osteoporotic fracture, are neither identified nor treated, further indicating that opportunities are being missed to address the management and treatment gaps of those affected by osteoporosis.”

Amgen and UCB resubmitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for romosozumab in July 2018. The European Medicines Agency (EMA) and the Pharmaceuticals and Medical Device Agency (PMDA) in Japan are currently reviewing marketing authorisation applications for romosozumab and interactions with the agencies are ongoing. Romosozumab is being co-developed by UCB and Amgen.

UCB/Amgen presentations:

- **T-score as an Indicator of Fracture Risk on Therapy: Evidence From Romosozumab vs Alendronate Treatment in the ARCH Trial** - Presentation number 1074, Oral Presentation, Sunday Sept. 30, 10:45-11:00 a.m. EDT
- **The Design and Validation of a New Algorithm to Identify Initial Incident and Recurrent Incident Fragility Fractures in Administrative Claims Data** – Presentation number SUN-0637, Poster Presentation, Sunday Sept. 30, 12:30-2:30 p.m. EDT
- **Multiple Missed Opportunities to Reduce Key Fragility Fractures: Can We Afford to Continue to Ignore the Facts?** – Presentation number SUN-0639, Poster Presentation, Sunday Sept. 30, 12:30-2:30 p.m. EDT

Collaboration Presentations:

- **Secular Trends in the Initiation of Therapy in Secondary Fracture Prevention: Widening Treatment Gaps in Denmark and Spain** – Presentation number FRI-0262, Plenary Poster Presentation, Friday Sept. 28 5:00-7:00 p.m.
- **Osteocytes Maintain Mechanosensing Following Long-Term Dosing with Sclerostin Antibody** – Presentation number MON-0995, Poster Presentation, Monday Oct. 1, 12:00-2:00 p.m. EDT

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

About EVENITY™* (romosozumab)
Romosozumab 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, which enables romosozumab to increase bone formation and reduce bone resorption simultaneously. Romosozumab has been studied for its to reduce the risk of fractures in an extensive global Phase 3 program. This program included two large fracture trials comparing romosozumab to either placebo or active comparator in more than 11,000 postmenopausal women with osteoporosis. Amgen and UCB are co-developing romosozumab.

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.

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 in immunology and neurology. With more than 7,500 people in approximately 40 countries, the company generated revenue of € 4.5 billion in 2017. 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. 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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