UCB News

RESULTS FROM PHASE 3 BRIDGE STUDY SHOWED ROMOSOZUMAB SIGNIFICANTLY INCREASED BONE MINERAL DENSITY IN MEN WITH OSTEOPOROSIS

- Romosozumab Data at the ACR/ARHP Annual Meeting Showed Significant Bone Mineral Density Gains at the Lumbar Spine, Total Hip and Femoral Neck Compared to Placebo at six and 12 Months

BRUSSELS, BELGIUM and THOUSAND OAKS, Calif. (14 November, 2016) - UCB (Euronext Brussels: UCB) and Amgen (NASDAQ:AMGN) today announced results from the Phase 3 BRIDGE study showing that in men with osteoporosis, the investigational agent romosozumab resulted in significant bone mineral density (BMD) gains at the lumbar spine, total hip and femoral neck compared to placebo at six and 12 months. The full findings were presented for the first time at the American College of Rheumatology (ACR) and Association of Rheumatology Health Professionals (ARHP) Annual Meeting in Washington, D.C., Nov. 11-16, 2016 (abstract #321).

Though more common in women, osteoporosis is also a serious health issue for men. One in five men over the age of 50 worldwide will have an osteoporosis-related fracture – an incidence that is greater than the development of prostate cancer.[1] Men are less likely to be diagnosed with osteoporosis and treated, while fractures can be associated with increased rates of disability compared to women.[1]

“Romosozumab has the ability to improve bone mass, structure and strength by both increasing bone formation and decreasing bone resorption,” said E. Michael Lewiecki, M.D., principal investigator for the BRIDGE study and clinical assistant professor of medicine, University of New Mexico School of Medicine, Albuquerque, NM. “These Phase 3 findings are particularly promising as they show the clinical effects of romosozumab in men with osteoporosis – a population that is often under-recognized and under-treated for a disease that can have devastating consequences.”

The BRIDGE study (place**B**o-cont**R**olled study evaluat**I**ng the efficacy an**D** safety of romosozumab in treatin**G** m**E**n with osteoporosis) involved 245 men with osteoporosis (163 romosozumab, 82 placebo) randomized 2:1 to receive either 210 mg romosozumab or placebo subcutaneously once monthly for 12 months. All subjects received daily calcium and vitamin D. The primary endpoint was met, with romosozumab demonstrating a statistically significant increase (12.1 percent; $p<0.01$) in BMD at the lumbar spine (as assessed by dual energy x-ray absorptiometry) compared with placebo at 12 months. All secondary endpoints were also met with romosozumab showing a statistically significant increase in BMD at total hip (2.5 percent) and the femoral neck (2.2 percent) at 12 months (both $p<0.01$ compared to placebo). A statistically significant increase in BMD at six months was also seen with romosozumab at all sites examined compared to placebo: lumbar spine (9.0 percent), total hip (1.6 percent), femoral neck (1.2 percent; $p<0.01$ for all sites). The dual effect of romosozumab was reflected by an increase in P1NP (86 percent median increase from baseline peaking at one month), a marker of bone formation, and a decrease in CTX (31 percent median decrease from baseline at one month), a marker of bone resorption.

The overall incidence of adverse events and serious adverse events were balanced between treatment groups. The most frequently reported adverse events (greater than five percent in the romosozumab arm) were nasopharyngitis, back pain, hypertension, headache and constipation. Injection site reactions were reported in 5.5 percent of patients in the romosozumab treatment group and 3.7 percent in the placebo group during the 12-month period. Most injection site reactions were reported as mild in severity. The patient incidence of

positively adjudicated cardiovascular serious adverse events was 4.9 percent (8/163) in the romosozumab group and 2.5 percent (2/81) in the placebo group. The subject incidence of positively adjudicated cardiovascular death was 0.6 percent (1/163) in the romosozumab group and 1.2 percent (1/81) in the placebo group.

UCB and Amgen plan to discuss the BRIDGE results with global regulators.

The BRIDGE study is part of the comprehensive Phase 3 program for romosozumab and complements positive results from two additional studies at the ACR/ARHP annual meeting focusing on romosozumab in postmenopausal women with osteoporosis - the FRAME study (abstract #1023) and the STRUCTURE study (abstract #1024).

References

1. *International Osteoporosis Foundation. Osteoporosis in Men. Available at https://www.iofbonehealth.org/osteoporosis-men. Accessed October 17, 2016.*

About Romosozumab

Romosozumab is an investigational bone-forming monoclonal agent and is not approved by any regulatory authority for the treatment of osteoporosis. It is designed to work by inhibiting the activity of the protein sclerostin and has a dual effect on bone, increasing bone formation and decreasing bone resorption. 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 postmenopausal women with osteoporosis. Amgen and UCB are co-developing romosozumab. In September 2016, UCB and Amgen announced that the U.S. Food and Drug Administration (FDA) accepted for review the Biologics License Application (BLA) for romosozumab for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

About the BRIDGE study

BRIDGE is a multi-center, international, randomized, double-blind, placebo-controlled study in men aged 55-90 years with a lumbar spine, total hip or femoral neck BMD T score ≤ -2.5 or ≤ -1.5 and a history of fragility nonvertebral fracture (excluding hip fracture) or vertebral fracture. The study evaluated the effectiveness of romosozumab treatment for 12 months, compared with placebo, in increasing BMD at the lumbar spine, as well as the effect on BMD at the femoral neck and total hip at 12 months and at six months, and the percent change from baseline in the serum bone turnover markers P1NP and CTX.

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 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 Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

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.

Forward-Looking Statements – Amgen

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. 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 metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products after they are on the market.

Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing its products and global economic conditions. In addition, sales of Amgen's products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify safety, side effects or manufacturing problems with its products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between it and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a

substantial amount of its commercial manufacturing activities at a few key manufacturing facilities and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all. Amgen is increasingly dependent on information technology systems, infrastructure and data security. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock.

The scientific information discussed in this news release relating to new indications for Amgen's products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

For further information

UCB

France Nivelle, Global Communications, UCB
T +32.2.559.9178, france.nivelle@ucb.com

Laurent Schots, Media Relations, UCB
T+32.2.559.92.64, Laurent.schots@ucb.com

Antje Witte, Investor Relations, UCB
T +32.2.559.94.14, antje.witte@ucb.com

Isabelle Ghellynck, Investor Relations, UCB
T+32.2.559.9588, isabelle.ghellynck@ucb.com

Amgen, Thousand Oaks

Kristen Davis, 805-447-3008 (media)

Kristen Neese, 805-313-8267 (media)

Arvind Sood, 805-447-1060 (investors)