



UCB AND AMGEN REPORT NEW DATA AT ENDO 2017 EXAMINING THE OPTION OF A SECOND COURSE OF TREATMENT WITH EVENITY™* (ROMOSOZUMAB)

BRUSSELS, BELGIUM and THOUSAND OAKS, Calif. (1 April, 2017) - UCB (Euronext Brussels: UCB) and Amgen (NASDAQ:AMGN) today announced results from the fourth year of a Phase 2 study showing the efficacy and safety of a second course of treatment with romosozumab, an investigational agent for postmenopausal women with osteoporosis. The results were presented in an oral session (OR08-1)¹ at ENDO 2017, the Endocrine Society's Annual Meeting in Orlando, Fla.

In the study, postmenopausal women with low bone mass (lumbar spine, total hip or femoral neck T score between -2.0 and -3.5) were initially randomized to various doses of romosozumab or placebo for 24 months and then re-randomized to receive denosumab or placebo for the next 12 months (24 to 36 months), as previously reported. For months 36 to 48 all of these patients were then treated with romosozumab (210 mg) for 12 months.

In patients who initially received 210 mg of romosozumab followed by placebo and then a second course of romosozumab (n=19), the second course led to significant increases in bone mineral density (BMD) to an extent similar to the initial romosozumab treatment: lumbar spine (12.7 percent), total hip (5.8 percent) and femoral neck (6.3 percent)² during months 36 to 48. In those patients who received a second course of romosozumab after denosumab, romosozumab further increased BMD by 2.8 percent at the lumbar spine, while maintaining BMD at the total hip and femoral neck.

"Since osteoporosis is a chronic condition which may lead to debilitating fractures, the option of providing a second course of bone-building therapy may benefit some patients with severe osteoporosis," said David L. Kendler, M.D., University of British Columbia, Vancouver, Canada and lead study investigator. "This latest study is important as it shows that the safety and efficacy of romosozumab extends from initial use to a second course of treatment."

A similar adverse event (AE) profile was observed in the romosozumab groups, regardless of prior treatment group (placebo or denosumab). In patients treated with romosozumab for months 36 to 48, serious AEs were reported for five percent of patients who initially received romosozumab (n=7/140) and four percent initially received placebo (n=1/27). The AEs reported by these patients for months 36 to 48 include hypersensitivity (7.4 percent, initial placebo; 7.9 percent, initial romosozumab), injection-site reactions (7.4 percent, initial placebo; 7.1 percent, initial romosozumab), malignancies (3.7 percent, initial placebo; 3.6 percent, initial romosozumab) and osteoarthritis (11.1 percent, initial placebo; 2.1 percent, initial romosozumab). There were no reports of osteonecrosis of the jaw or atypical femoral fracture.

In the same oral session, Amgen and UCB presented results from a separate analysis of the Phase 2 study (OR08-2)³ showing BMD gains from prior romosozumab treatment were generally maintained for two years (months 48 to72) when followed by a single dose of zoledronic acid.





The pivotal romosozumab Phase 3 studies have all been designed with patients receiving 12 months (single course) of romosozumab followed by treatment with an anti-resorptive therapy.

About 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 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.

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 € 4.2 billion in 2016. 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.

For more information, visit <u>www.amgen.com</u> and follow Amgen on www.twitter.com/amgen.

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.

Amgen Forward-Looking Statements

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 our 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 we project. 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 us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop 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 we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products after they are on the market.

Our results may be affected by our 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 our products and alobal economic conditions. In addition, sales of our 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, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and pavers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to acquire other companies or products and to integrate the operations of





companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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References

¹Kendler DL, et al. (2017, April). Retreatment With Romosozumab After 12 Months of Placebo Demonstrates Similar BMD Efficacy Compared With Initial Romosozumab Treatment. Oral presentation conducted at the annual meeting of the Endocirine Society, Orlando, FL.

²Kendler DL, et al. (2017, April). Retreatment With Romosozumab After 12 Months of Placebo Demonstrates Similar BMD Efficacy Compared With Initial Romosozumab Treatment. Abstract available at: https://plan.core-apps.com/tristar_endo17/abstract/9f6300891abea35983bbd25dffe74ee9.

³McClung MR, et al. (2017, April). *Transition to Zoledronic Acid After Romosozumab Treatment Maintains Bone Mineral Density Gains.* Oral presentation conducted at the annual meeting of the Endocirine Society, Orlando, FL.

