Amgen And UCB Present Positive Data At ENDO 2016 Comparing Romosozumab With Teriparatide

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In Phase 3 Open-Label STRUCTURE Study Postmenopausal Women With Osteoporosis Transitioning From Oral Bisphosphonates to Romosozumab Experienced Consistent and Significant Gains in Bone Mass and Estimated Strength Over Teriparatide

THOUSAND OAKS, Calif. and BRUSSELS, April 1, 2016 /PRNewswire/ -- Amgen (NASDAQ: AMGN) and UCB (Euronext Brussels: UCB) today announced detailed Phase 3 results showing the investigational agent romosozumab demonstrated a statistically significant increase in hip bone mineral density (BMD) and strength compared with teriparatide in postmenopausal women with osteoporosis transitioning from bisphosphonate treatment. The data, from the randomized, open-label, international, multi-center STRUCTURE study (**ST**udy evaluating effect of **R**omosoz**U**mab **C**ompared with **T**eriparatide in postmenopa**U**sal women with osteoporosis at high risk for fracture p**R**eviously treated with bisphosphonat**E** therapy), were presented during an oral session at ENDO 2016, the Endocrine Society's 98th Annual Meeting & Expo in Boston.

"These findings are especially important because they show romosozumab provided significant improvements in hip bone strength in a population that remained at high risk of fracture despite bisphosphonate therapy," said Bente Langdahl, Ph.D., DMSc, professor at the department of endocrinology and internal medicine at the Aarhus University Hospital in Denmark and STRUCTURE investigator. "Across the primary and secondary endpoints, patients transitioning from oral bisphosphonates to romosozumab showed consistent and significant gains in bone mass and estimated strength over teriparatide. At the hip, patients transitioning to teriparatide showed either no gains or significant decreases in these parameters."

The trial included 436 women, averaging 72 years of age, with postmenopausal osteoporosis, a history of non-vertebral fracture after the age of 50, or vertebral fracture and treatment with bisphosphonate therapy for a minimum of three years prior to transitioning to romosozumab or teriparatide therapy. The women were randomly assigned to receive either subcutaneous romosozumab 210 mg once monthly (n=218) or subcutaneous teriparatide 20 mcg daily for 12 months (n=218).

The results showed that the percent change from baseline in BMD at the total hip through month 12 (the primary endpoint, an average of the percent change from baseline at month six and 12), was significantly greater with romosozumab compared with teriparatide: 2.6 percent versus –0.6 percent, respectively (p<0.0001), for a mean difference between the two groups of 3.2 percent (p<0.0001). The measurement was based on the standard method of dual-energy x-ray absorptiometry (DXA).

For the secondary endpoints, patients treated with romosozumab had significantly larger increases from baseline in BMD and strength compared with those taking teriparatide, with mean differences ranging from 3.1 percent to 4.6 percent (all p-values <0.0001):

Percent change from baseline	Romosozumab	Teriparatide	Mean Difference
Total hip BMD changes by DXA at six months	2.3 percent	–0.8 percent	3.1 percent
Total hip BMD changes by DXA at 12 months	2.9 percent	–0.5 percent	3.4 percent
Femoral neck BMD changes by DXA at six months	2.1 percent	–1.1 percent	3.2 percent
Femoral neck BMD changes by DXA at 12 months	3.2 percent	–0.2 percent	3.4 percent
Lumbar spine BMD changes by DXA at six months	7.2 percent	3.5 percent	3.8 percent
Lumbar spine BMD changes by DXA at 12 months	9.8 percent	5.4 percent	4.4 percent
Total hip integral BMD changes by quantitative computed tomography (QCT) at six months	2.3 percent	–0.8 percent	3.1 percent
Total hip integral BMD changes by QCT at 12 months	3.4 percent	–0.2 percent	3.6 percent
Total hip cortical BMD changes by QCT at six months	0.7 percent	–2.7 percent	3.4 percent
Total hip cortical BMD changes by QCT at 12 months	1.1 percent	–3.6 percent	4.6 percent
Total hip estimated strength by finite element analysis (FEA) at six months	2.1 percent	–1.0 percent	3.1 percent
Total hip estimated strength by FEA at 12 months	2.5 percent	–0.7 percent	3.2 percent

The overall incidence of adverse events was generally balanced between the two study arms. Incidence of all adverse events in patients treated with romosozumab was 75.2 percent compared to 69.2 percent with teriparatide. Serious adverse events occurred in 7.8 percent of patients treated with romosozumab compared to 10.7 percent for teriparatide. Adverse events reported in the romosozumab arm greater than or equal to 10 percent of patients were arthralgia and nasopharyngitis. Injection site reactions were reported in 7.8 percent.

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, and has a dual effect on bone, both 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 postmenopausal women with osteoporosis. Amgen and UCB are co-developing romosozumab.

About the STRUCTURE study (NCT01796301)
STRUCTURE (**ST**udy evaluating effect of **R**omosoz**U**mab **C**ompared with **T**eriparatide in postmenopa**U**sal women with osteoporosis at high risk for fracture p**R**eviously treated with bisphosphonat**E** therapy) was a Phase 3, multi-center, international, randomized, open-label, teriparatide-controlled study that evaluated safety, tolerability and efficacy of romosozumab in women with postmenopausal osteoporosis. The trial included 436 postmenopausal women averaging 72 years of age who had postmenopausal osteoporosis and a history of bone fracture; patients were treated with bisphosphonate therapy for a minimum of three years prior to screening, with treatment with alendronate (70 mg weekly or equivalent) during the year immediately prior to screening. The women received daily calcium and vitamin D and were randomly assigned to receive either subcutaneous

romosozumab 210 mg once monthly (n=218), administered by a healthcare professional, or self-administered subcutaneous teriparatide 20 mcg daily for 12 months (n=218).

The primary endpoint was percent change from baseline in total hip BMD by DXA through month 12 (average of the changes at months six and 12). Key secondary endpoints included percent change from baseline at months six and 12 in total hip BMD by DXA; hip integral and cortical BMD by quantitative computed tomography (QCT), a method to measure BMD changes in three dimensions; and estimated hip strength by finite element analysis (FEA). FEA is a validated method that utilizes QCT scans to simulate compression overload to estimate vertebral strength, and a sideways fall to estimate femoral strength. Other secondary endpoints included lumbar spine and femoral neck BMD by DXA at months six and 12.

About Osteoporosis

Osteoporosis affects many women after menopause as their ability to form new bone cannot counter balance the rate at which bone is being removed.[1,2] This bone loss leads to weakened bones over time, increasing the potential for a break.[3]

It is estimated that one in three women over the age of 50 will experience an osteoporotic fracture.[4,5] Patients who experience an osteoporosis-related fracture are twice as likely to experience a future fracture.[6]

The World Health Organization has officially declared osteoporosis a public health crisis,[7,8] and the International Osteoporosis Foundation urges governments worldwide to make osteoporosis a healthcare priority.[9]

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 biologics manufacturing 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 www.amgen.com and follow us on www.twitter.com/amgen.

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 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 global 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. 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 or European Commission, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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 8500 people in approximately 40 countries, the company generated revenue of € 3.3 billion in 2014. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

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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