



## New Exploratory Analysis Showed Romosozumab Increased Estimated Bone Strength More Than Teriparatide

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### Exploratory Sub-Study Data From Phase 2 Trial Showed Romosozumab Increased Estimated Bone Strength at the Spine and Hip in Postmenopausal Women With Low Bone Mass More Than Open-Label Teriparatide as Measured by Finite Element Analysis

THOUSAND OAKS, Calif. and BRUSSELS, Oct. 12, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN) and UCB (Euronext Brussels: UCB) today presented additional findings from an exploratory sub-study of the previously reported romosozumab Phase 2 trial.<sup>1</sup> The findings were presented today in an oral plenary session at the American Society for Bone and Mineral Research (ASBMR) 2015 Annual Meeting in Seattle.

The small exploratory sub-study data showed that, at month 12, the investigational bone-forming agent romosozumab increased estimated bone strength (percent change from baseline) at the spine and hip more than open-label teriparatide in postmenopausal women with low bone mass. These results were measured by a validated method called finite element analysis (FEA), which utilized quantitative computed tomography (QCT) scans to simulate compression overload to estimate vertebral strength, and a sideways fall to estimate femoral strength.<sup>2</sup>

"Engineers and physicists have long used finite element analysis to better understand the structural integrity and failure of physical objects when subjected to load," said lead investigator Tony M. Keaveny, Ph.D., professor of Mechanical Engineering and Bioengineering at the University of California, Berkeley. "By applying this analysis to bone scans of postmenopausal women with low bone mass, we were able to integrate the information we had on bone mineral density and structure to estimate bone strength in those treated with romosozumab."

The FEA showed that, at the spine, women in the romosozumab group (210 mg once monthly, n=24) increased estimated strength compared to baseline by 27.3 percent at month 12, which was greater than placebo (-3.9 percent, n=27) and teriparatide (18.5 percent, n=28).<sup>2</sup> At the hip, the estimated strength increased from baseline by 3.6 percent with romosozumab (n=9), compared with placebo (-0.1 percent, n=18) or teriparatide (-0.7 percent, n=19).<sup>2</sup>

These data are from a small exploratory sub-study (n=79) of a Phase 2 trial (NCT00896532) that included a total of 419 patients. A subset of these women underwent spine and hip QCT imaging to measure bone mineral density (BMD) gains.<sup>3</sup> To investigate the effects of romosozumab on bone strength an FEA was performed on these QCT scans.

"The strength improvements observed with romosozumab in this trial – and documented using a validated method for assessing fracture risk and monitoring treatment – further support its potential as a treatment option for patients at high risk for fracture," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "These important new data support our extensive global Phase 3 program of romosozumab, and we look forward to advancing this research to help provide a potential new treatment option for appropriate patients."

Adverse events in the original Phase 2 study were similar across groups, except for mild, generally non-recurring injection site reactions observed more frequently with romosozumab compared to placebo, but with no observed dose-related relationship. The most common adverse events included mild upper respiratory tract infection, pain in the back and joints, and headache. These reactions did not lead to study drug discontinuation or study withdrawal; the safety of romosozumab will be further addressed in subsequent larger studies.

"These data illustrate the potential impact of building bone through both increasing bone formation and decreasing bone resorption as romosozumab has demonstrated in skeletal regions of interest. These sub-study results reinforce our confidence in the ability of romosozumab to build bone strength as well as density and we look forward to reporting the outcomes of the first fracture study in 2016," said Professor Dr. Iris Loew-Friedrich, chief medical officer and executive vice president at UCB.

#### About Finite Element Analysis

Finite element analysis (FEA) is a computer model of a material or design that is stressed and analyzed and tested for specific results. This involves breaking down an object into a large number of finite elements (e.g., small cubes), and using mathematical equations to help predict the behavior of each element. These behaviors are then calculated by a computer to predict the behavior of the object as a whole.

FEA has been applied for the past 40 years to simulate the mechanical behavior of bone, helping to predict strength at major fracture sites, like the lumbar spine and femoral hip.

#### 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 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 evaluating the safety and efficacy of romosozumab includes two large fracture trials comparing romosozumab to either placebo or active comparator in more than 10,000 postmenopausal patients with osteoporosis. Primary results from the Phase 3 study FRAME are expected in the first half of 2016. Romosozumab is being co-developed by Amgen and UCB.

#### 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 largest 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](http://www.amgen.com) and follow us on [www.twitter.com/amgen](https://www.twitter.com/amgen).

## **About UCB**

UCB, Brussels, Belgium ([www.ucb.com](http://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 - Amgen**

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen or us) and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. 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 (SEC) reports filed by Amgen Inc., including Amgen Inc.'s most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen Inc.'s most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of Oct. 12, 2015, and expressly disclaims any duty to update information contained in this news release.

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 and our partners to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. 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 business may be impacted by government investigations, litigation and product liability claims. 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. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products (including products of our wholly-owned subsidiaries) are affected by the 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 as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, while we and our partners routinely obtain patents for products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, 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 integrate the operations of companies we have acquired may not be successful. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our ongoing restructuring plan. 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 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.

## **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.

CONTACT: Amgen, Thousand Oaks  
Kristen Davis, 805-447-3008 (media)  
Kristen Neese, 805-313-8267 (media)  
Arvind Sood, 805-447-1060 (investors)

CONTACT: UCB, Brussels  
France Nivelles, Global Communications, UCB  
T +32.2.559.9178, [france.nivelles@ucb.com](mailto:france.nivelles@ucb.com)  
Laurent Schots, Media Relations, UCB  
T+32.2.559.92.64, [Laurent.schots@ucb.com](mailto:Laurent.schots@ucb.com)  
Antje Witte, Investor Relations, UCB  
T +32.2.559.94.14, [antje.witte@ucb.com](mailto:antje.witte@ucb.com)

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<sup>1</sup> McClung MR, Grauer A, Boonen S, et al. Romosozumab in postmenopausal women with low bone mineral density. *N Engl J Med*. 2014 Jan 30;370(5):412-20.

<sup>2</sup> Keaveny TM et al. Romosozumab improves strength at the lumbar spine and hip in postmenopausal women with low bone mass compared with teriparatide. Abstract 1143, Oral Presentation, ASBMR, October 2015.

<sup>3</sup> Genant KH et al. Effect of Romosozumab on Lumbar Spine and Hip Volumetric Bone Mineral Density (vBMD) as Assessed by Quantitative Computed Tomography (QCT). Presentation Number: 1022, ASBMR October 2013.



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