

# UCB and Amgen Initiate Sclerostin Antibody Phase 3 Program in Patients With Postmenopausal Osteoporosis

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## First Patient Randomized Marks Start of Phase 3 Program to Evaluate Safety and Efficacy of CDP7851/AMG 785 in Women With Postmenopausal Osteoporosis

BRUSSELS and THOUSAND OAKS, Calif., April 4, 2012 /PRNewswire/ -- UCB (Euronext Brussels: UCB) and Amgen (NASDAQ:AMGN) announced today the start of their sclerostin antibody (CDP7851/AMG 785) Phase 3 clinical trial program for the treatment of postmenopausal osteoporosis.

"We look forward to working with UCB on the CDP7851/AMG 785 Phase 3 program," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Despite available osteoporosis therapies, there remains a significant need for additional treatment options that form new bone in women diagnosed with postmenopausal osteoporosis."

"Our sclerostin antibody project with Amgen is one of the most exciting pipeline programs in UCB's portfolio. Data collected so far indicate the potential for a change of treatment paradigms in postmenopausal osteoporosis," said Prof. Dr. med. Iris Loew-Friedrich, Chief Medical Officer of UCB and Executive Vice-President Global Projects and Development. "We are delighted about the start of the Phase 3 program. The progress made to date encourages and motivates us as we work toward providing a new treatment option for women living with postmenopausal osteoporosis."

The Phase 3 program includes a multicenter, international, randomized, double-blind, placebo-controlled, parallel-group, two-year study in more than 5,000 postmenopausal women with osteoporosis. The primary endpoint will evaluate the incidence of new vertebral fractures at 12 months. Initial results from the Phase 3 program are expected by the end of 2015.

CDP7851/AMG 785 is a humanized monoclonal antibody that binds to and inhibits sclerostin, a protein secreted by bone cells that inhibits bone formation. By binding to and blocking sclerostin, CDP7851/AMG 785 is designed to increase the amount of bone in the skeleton. With more than 75 million people worldwide suffering from osteoporosis, there is a serious patient need for therapeutics that help build bone. Amgen and UCB are collaborating on the development of CDP7851/AMG 785 for the treatment of bone-related conditions, including postmenopausal osteoporosis and fracture healing.

#### **About Postmenopausal Osteoporosis**

Osteoporosis is the most common disorder of bone metabolism. Osteoporosis, or porous bone, is a chronic, progressive and systemic disease marked by low bone mass, deterioration of bone tissue and low bone strength, leading to bone fragility and an increased risk of fractures. The rate of bone loss is accelerated in women during and after the menopause as a result of estrogen deficiency associated with the loss of ovarian function at menopause. The risk of fracture increases exponentially with age. The prevalence of osteoporosis is estimated to be 64.6 million people in the seven major markets; women are four times more likely than men to develop osteoporosis.

#### **About UCB**

UCB, Brussels, Belgium (<a href="www.ucb.com">www.ucb.com</a>) 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 8,000 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2011. UCB is listed on Euronext Brussels (symbol: UCB).

### **UCB Forward-looking statement**

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.

#### **About Amgen**

Amgen discovers, develops, manufactures, and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen

therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit <a href="https://www.amgen.com">www.twitter.com/amgen.</a>. Follow us on <a href="https://www.amgen.com">www.twitter.com/amgen.</a>.

#### **Amgen Forward-Looking Statements**

This statement contains forward-looking statements that are based on management's current expectations and beliefs 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, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen'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 April 4, 2012 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 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 products liability claims. 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 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 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 and there can be no guarantee of our 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.

The scientific information discussed in this statement related to our product candidates is preliminary and investigative and is not part of the labeling approved by the U.S. FDA or the European Medicines Agency (EMA) 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. Only the FDA, EMA or other applicable regulatory bodies can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the approved labeling for the products, and not the information discussed in this statement.

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