

# Amgen and UCB Announce Positive Phase 2 Results of AMG 785/CDP7851 in Patients With Postmenopausal Osteoporosis (PMO)

April 21, 2011

## **Top-line Results Met Primary Endpoint**

THOUSAND OAKS, Calif. and BRUSSELS, April 21, 2011 /PRNewswire via COMTEX/ --

Amgen (NASDAQ: AMGN) and UCB (Euronext Brussels: UCB) announced today positive top-line results from their Phase 2 clinical study comparing sclerostin-antibody AMG 785/CDP7851 to placebo in postmenopausal women with low bone mineral density (BMD) for the treatment of postmenopausal osteoporosis (PMO).

This Phase 2 study met its primary endpoint, demonstrating significant increases in lumbar spine bone mineral density at month 12 for the AMG 785/CDP7851 active arms versus the placebo arm. In addition, AMG 785/CDP7851 compared positively with the two active comparators, teriparatide and alendronate.

The overall incidence of adverse events was generally balanced between groups. Consistent with previous studies, injection site reactions were reported more frequently in those patients receiving AMG 785/CDP7851.

"We are very encouraged by the results of this study," said Roger M. Perlmutter, M.D., Ph.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 with postmenopausal osteoporosis. We look forward to working with UCB to advance the AMG 785/CDP7851 program into Phase 3."

"The AMG 785/CDP7851 project with Amgen is one of the most exciting pipeline programs in UCB's immunology disease portfolio. The favorable comparison with established therapies indicates the potential for a change of treatment paradigms with AMG 785/CDP7851 in PMO," said Prof. Dr. med. Iris Loew-Friedrich, chief medical officer of UCB and executive vice-president Global Projects and Development. "We will now begin the in depth analysis of the data to prepare for the Phase 3 program. The results fuel our energy working towards providing a new treatment option for the millions of women living with PMO."

The 12-month Phase 2 study is a multi-center, international, randomized, placebo-controlled, parallel-group study designed to evaluate the effect of AMG 785/CDP7851 compared to placebo in women with low BMD, and to characterize the safety and tolerability of AMG 785/CDP7851. Approximately 400 postmenopausal women with low BMD (T-scores between -2.0 and -3.5) are enrolled in the study. Treatment arms included dosing at 70, 140 and 210 mg subcutaneously once a month, and 140 and 210 mg every three months, against matched placebo for all treatment groups.

Detailed results will be submitted for presentation at a future medical congress.

AMG 785/CDP7851 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, AMG 785/CDP7851 is designed to allow the body to add more bone to the skeleton. Amgen and UCB have collaborated for the development of AMG 785/CDP7851 for the treatment of bone-related conditions, including PMO and fracture healing.

### 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, 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 vital medicines, visit <u>www.amgen.com</u>.

#### About UCB

UCB, Brussels, Belgium (<u>www.ucb.com</u>) 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 2010. 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. Such statements are subject to risks and uncertainties that may cause actual results to be materially different 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, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.

#### **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 21, 2011 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 products. 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.

CONTACT: Amgen, Thousand Oaks Christine Regan: +1 (805) 447-5476 (Media) Arvind Sood: +1 (805) 447-1060 (Investors)

CONTACT: UCB, Brussels Antje Witte, Investor Relations UCB T +32.2.559.9414, antje.witte@ucb.com Michael Tuck-Sherman, Investor Relations, UCB T +32.2.559.9712, michael.tuck-sherman@ucb.com Nancy Nackaerts, External Communications, UCB M: +32 473 86 44 14, nancy.nackaerts@ucb.com Scott Fleming, Global Communications Manager UCB- Immunology T +44.770.277.7378, Scott.fleming@ucb.com

(Logo: http://photos.prnewswire.com/prnh/20081015/AMGENLOGO)

(Logo: http://photos.prnewswire.com/prnh/20110421/LA87263LOGO)

SOURCE Amgen