



## FDA Grants Priority Review Designation to Denosumab Biologics License Application for the Reduction of Skeletal Related Events in Advanced Cancer Patients

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### FDA Accepts Submission Which Includes Data from Three Pivotal Phase 3 Trials

THOUSAND OAKS, Calif., July 16, 2010 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN) today announced that the U.S. Food and Drug Administration (FDA) has granted priority review designation to denosumab, a subcutaneous RANK Ligand inhibitor, for the treatment of bone metastases to reduce skeletal related events (SREs) in patients with cancer. Filed in mid-May with the FDA, the Biologics License Application (BLA) submission summarizes clinical experience from nearly 6,900 patients across 18 clinical studies, including approximately 5,700 patients with advanced cancer in the three pivotal Phase 3 head-to-head trials versus Zometa(R) (zoledronic acid).

Priority review designation is granted to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. Consistent with priority review guidelines, the FDA will target an Agency action within six months of the application submission date, resulting in a Prescription Drug User Fee Act (PDUFA) action date of Thursday, November 18.

"Many cancer patients with skeletal metastases suffer debilitating complications, despite receiving the best available therapies," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "In clinical trials, denosumab has consistently demonstrated an ability to reduce the burden of complications from skeletal metastases, with a positive benefit-risk profile. We believe that this priority review designation underscores the potential for denosumab to provide a meaningful advance over the current standard of care for patients with metastatic bone disease."

Bone metastases, the spread of tumors to the skeleton, are a serious concern for many patients with advanced cancer. When cancer spreads to the bone, the growing cancer cells weaken and destroy the bone around the tumor, often producing serious clinical consequences such as fractures, spinal cord compression, or the need to receive radiation or surgery to bone. These events are collectively called SREs. The RANK/RANKL pathway is believed to play a central role in cancer-induced bone destruction, regardless of cancer type. Denosumab is the first therapy to target this important pathway.

Amgen has also submitted marketing applications in the European Union, Australia, Canada and Switzerland. In Japan, Amgen is working with our licensing partner, Daiichi-Sankyo Limited and a submission is planned in the near future.

#### **Bone Metastases: Prevalence and Impact**

Bone metastases occur in more than 1.5 million patients with cancer worldwide and are most commonly associated with cancers of the prostate, lung, and breast, with incidence rates as high as 75 percent of patients with metastatic disease [i].

The economic burden of U.S. patients with bone metastases is significant and is estimated to be \$12.6 billion annually [ii]. Patients with bone metastases who experience an SRE incur significantly higher medical costs compared with those who do not experience an SRE [iii].

#### **About Denosumab and Amgen's Research in Bone Biology**

Denosumab is the first fully human monoclonal antibody in late stage clinical development that specifically targets RANK Ligand, the essential regulator of osteoclasts (the cells that break down bone). The denosumab development program is the largest ever initiated by Amgen. This broad and deep development program demonstrates Amgen's commitment to researching and delivering pioneering medicines to patients with unmet medical needs. Amgen is studying denosumab in numerous tumor types across the spectrum of cancer-related bone diseases. Over 11,000 patients have been enrolled in the denosumab oncology clinical trials, testing the drug for the reduction of SREs in patients with breast and prostate cancer, as well as other solid tumors and multiple myeloma, for the amelioration of treatment-induced bone loss in patients with non-metastatic breast or prostate cancers, and for its potential to delay bone metastases in prostate cancer.

#### **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, 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 <http://www.amgen.com/>.

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

This news release 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 July 16, 2010 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 payors, 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 health care 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 news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (FDA) 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 can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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[i] Coleman RE and Brown. Skeletal complications of malignancy. *Cancer Suppl.* 1997; 80(8):1588

[ii] Schulman K and Kohles J. *Cancer.* 2007;109:2334-2342.

[iii] GVD/Barber ISPOR 2008 Poster; Schulman 2007; Delea et al. 2006.

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