Top-Line Results Announced of Pivotal Phase 3 Motesanib Trial in Advanced Non-Squamous Non-Small Cell Lung Cancer Patients

March 30, 2011

THOUSAND OAKS, Calif., CAMBRIDGE, Mass. and OSAKA, Japan, March 30, 2011 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN), Millennium: The Takeda Oncology Company, and Takeda Pharmaceutical Company Limited (TSE: 4502) today announced top-line results from the MONET1 pivotal Phase 3 trial evaluating motesanib administered in combination with paclitaxel and carboplatin in 1,090 patients with advanced non-squamous non-small cell lung cancer (NSCLC). The trial did not meet its primary objective of demonstrating an improvement in overall survival (OS) (hazard ratio 0.90, 95 percent CI 0.78 - 1.04, p=0.14).

"We are disappointed with the results from this trial, but look forward to further analysis of the data which may ultimately help inform future research in this area," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen.

"We thank the patients, caregivers, and investigators for their participation and engagement in the clinical evaluation of motesanib worldwide," said Nancy Simonian, M.D., chief medical officer, Millennium. "These disappointing results support the need for new treatments to address the unmet need in advanced non-squamous NSCLC."

Overall, the adverse event profile for motesanib was consistent with that seen in previous motesanib studies in NSCLC. Notable adverse events reported included hypertension, GI events (abdominal pain, diarrhea, nausea, and vomiting), gallbladder events (cholecystitis, gallbladder enlargement), fatigue, and hematological events (neutropenia, thrombocytopenia). Serious adverse events were more frequently reported in the motesanib arm.

Detailed results will be submitted for presentation at an upcoming medical congress.

Study Design

MONET1 (**MO**tesanib **N**SCLC **E**fficacy and **T**olerability Study) is a Phase 3, multicenter, randomized, placebo-controlled, double-blind trial that enrolled more than 1,000 men and women with NSCLC. Patients were randomized to receive either paclitaxel (200 mg/m2 IV Q3W), carboplatin (target AUC of 6 mg/mL x min IV Q3W), and motesanib (125 mg PO QD) or paclitaxel, carboplatin, and placebo. The primary endpoint of the study was OS, and secondary endpoints included progression-free survival (PFS), objective response rate (ORR), association of placental growth factor with OS, duration of response, and safety and tolerability.

About Motesanib

Motesanib is an investigational, orally-administered small molecule antagonist of vascular endothelial growth factor receptors 1, 2, and 3, platelet-derived growth factor receptors, and stem cell factor receptor.

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 www.amgen.com.

About Takeda

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive toward better health for patients worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, http://www.takeda.com.

About Millennium

Millennium: The Takeda Oncology Company, a leading biopharmaceutical company based in Cambridge, Mass., markets a first-in-class proteasome inhibitor, and has a robust clinical development pipeline of product candidates. Millennium Pharmaceuticals, Inc. was acquired by Takeda Pharmaceutical Company Ltd. ("Takeda", TSE: 4502) in May, 2008. The Company's research, development and commercialization activities are focused in oncology. Additional information about Millennium is available through its website, www.millennium.com.

Amgen Forward-Looking Statements

This news release contains forward-looking statements that are based on Amgen'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 Amgen's business. Unless otherwise noted, Amgen is providing this information as of March 30, 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 Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with Amgen's products after they are on the market. Amgen's business may be impacted by government investigations, litigation and products liability claims. Amgen depends on third parties for a significant portion of its manufacturing capacity for the supply of certain of its current and future products and limits on supply may constrain sales of certain of its current products and product candidate development.

In addition, sales of Amgen's 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 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 Amgen's products. In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Amgen believes that some of its newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen's products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with its products. In addition, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for its products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of its existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of its products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's business and results of operations.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Healthcareprofessionals shouldrefer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

Takeda and Millennium Forward-Looking Statements

This press release contains forward-looking statements regarding Takeda / Millennium's current plans, outlook, strategies, and results for the future. All forward-looking statements are based on judgments derived from the anticipated information available to Takeda / Millennium at this time. Forward looking statements can sometimes be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "continue," "seek," "pro forma," "potential," "target, " "forecast," or "intend" or other similar words or expressions of the negative thereof. Certain risks and uncertainties could cause Takeda / Millennium's actual results to differ materially from any forward looking statements contained in this press release. These risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda / Millennium's business, including general economic conditions in the US and worldwide; (2) competitive pressures; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) decisions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates; and (8) integration activities with acquired companies.

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