Independent Data Monitoring Committee Recommends Resuming Enrollment of Non-Squamous NSCLC Patients in the Motesanib MONET1 Trial

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THOUSAND OAKS, Calif. and CAMBRIDGE, Mass., Feb. 11 and OSAKA, Japan (Feb. 12, 2009) /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN), Millennium: The Takeda Oncology Company, and its parent company Takeda Pharmaceutical Company Limited (TSE:4052) today announced the Independent Data Monitoring Committee (DMC) for the MONET1 trial has recommended the trial resume enrollment of patients with non-squamous non-small cell lung cancer (NSCLC) following a three-month enrollment suspension. MONET1 is a Phase 3 study evaluating motesanib (AMG 706) in combination with paclitaxel and carboplatin for the first-line treatment of advanced NSCLC. Motesanib is part of a co-development program between Amgen, Millennium and Takeda.

The recent DMC guidance recommends the trial be re-opened only to patients with non-squamous cell histology. Non-squamous cell NSCLC is a histological subtype of NSCLC representing approximately two-thirds of the study population. Amgen, Millennium and Takeda plan to follow this recommendation which will require modifications to the study design of MONET1. Enrollment will resume once these changes are sanctioned by appropriate global health authorities.

In November 2008 the DMC recommended treatment discontinuation in subjects with squamous histology, and enrollment suspension in subjects with non-squamous histology. This recommendation was based on an observation of higher early mortality rates in the motesanib group compared to the placebo group and a higher incidence of hemoptysis in the squamous population. Patients with non-squamous NSCLC receiving motesanib were allowed to continue treatment during the temporary suspension.

"We endorse the DMC's decision to include only patients with non-squamous cell tumors in MONET1," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "This decision gives us confidence we have selected the right patient population to explore the clinical potential of motesanib in non-small cell lung cancer."

"NSCLC continues to be an area where new and effective therapies are needed, and we are optimistic about the potential of motesanib in patients with non-squamous NSCLC," said Nancy Simonian, M.D., chief medical officer, Millennium: The Takeda Oncology Company. "We are pleased with the DMC recommendation and will work with appropriate regulatory agencies and investigators to resume enrollment as soon as possible."

MONET1 (Motesanib NSCLC Efficacy and Tolerability Study) Trial Design

The primary endpoint is overall survival, and secondary endpoints include progression-free survival, objective response rate in patients with measurable disease, duration of response and safety. Patients were randomized 1:1 to receive paclitaxel and carboplatin administered every three weeks with or without 125 mg motesanib taken daily.

About Motesanib

Co-developed by Amgen, Takeda Pharmaceutical Company and Millennium: The Takeda Oncology Company, motesanib is an investigational, highly selective, oral agent that is being evaluated for its ability to inhibit angiogenesis by targeting vascular endothelial growth factor receptors 1, 2 and 3 (VEGFR1-3). It is also under investigation for its potential direct anti-tumor activity by targeting a family of proteins called tyrosine kinases, including platelet-derived growth factor receptor (PDGFR), and stem cell factor receptor (c-kit), two proteins involved in cell proliferation.

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 www.amgen.com.

About Takeda

Located in Osaka, Japan, Takeda Pharmaceutical Company Limited (TSE:4502) 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 striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products. 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 VELCADE, 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 Limited in May 2008. The Company's research, development and commercialization activities are focused in oncology. Additional information about Millennium is available through its website, http://www.millennium.com.

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 Feb. 11, 2009 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.

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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. Further, the scientific information discussed in this news release relating to new indications for Amgen's 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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