Amgen, Takeda and Millennium Provide Update on Phase 3 Trial of Motesanib in Patients With Non-Small Cell Lung Cancer

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THOUSAND OAKS, Calif., Nov. 19 /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN) and Millennium: The Takeda Oncology Company, a subsidiary of Takeda Pharmaceutical Company Limited (TSE: 4052), today announced that enrollment in the Phase 3 MONET1 trial evaluating motesanib (AMG 706) in combination with paclitaxel and carboplatin for the first-line treatment of advanced non-small cell lung cancer (NSCLC) has been temporarily suspended following a planned safety data review of 600 patients by the study's independent Data Monitoring Committee (DMC). Motesanib is part of a broad co-development program between Amgen and Takeda.

The DMC recommended that enrollment in the study, which allowed both squamous and non-squamous NSCLC patients, be suspended based on an observation of higher early mortality rates in the motesanib group compared to the placebo group. In addition, the DMC recommended that the patients with squamous NSCLC immediately discontinue motesanib therapy based on an observation of a higher incidence of hemoptysis. The DMC did not recommend discontinuation of motesanib therapy for the patients with non-squamous NSCLC. The DMC will review updated data after three months.

Amgen, in collaboration with Takeda Bio Development Center, is implementing both of the DMC's recommendations and notifying worldwide regulatory agencies, including the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMEA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), as well as motesanib clinical investigators.

"While we are disappointed in this outcome, it is consistent with data seen with some other anti-VEGF therapies and appears to constitute a class effect of these types of agents," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "Patient safety is our top priority, hence we have acted quickly to implement the recommendations of the DMC. Working with our development partner, Takeda, we will continue to evaluate the therapeutic potential of motesanib in non-squamous NSCLC and metastatic breast cancer, as well as in other solid tumors."

"NSCLC continues to be an area where new and effective therapies are needed. We look forward to the follow up recommendations from the DMC in order to chart the best path forward for the development of this molecule," said Nancy Simonian, M.D., chief medical officer, Millennium: The Takeda Oncology Company.

MONET1 (Motesanib NSCLC Efficacy and Tolerability Study) Trial Design

This Phase 3, multicenter, randomized, placebo-controlled, double-blind trial has enrolled 1,100 of 1,240 planned patients with advanced NSCLC. Patients with either squamous or non-squamous NSCLC were allowed in this study. Squamous NSCLC is a histological subtype of NSCLC and accounts for approximately one-third of the study population. 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 carboplatin and paclitaxel 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 disorder, 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.

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 novel cancer product, and has a robust clinical development pipeline of product candidates. Millennium Pharmaceuticals, Inc. was acquired by Takeda Pharmaceutical Company Ltd. 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 Statement

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 Nov. 19, 2008 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 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 news release related to our 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 our products is preliminary and investigative and is not part of the labeling approved by the 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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