



Amgen Presents New Data at ASCO on Four Investigational Molecules from Oncology Pipeline

May 31, 2008

Early Data from Apoptosis, Angiogenesis and Growth Regulation Programs Suggest Biologic Activity in a Range of Tumor Types

Abstract Numbers 3570, 2051, 3583 and 3539

CHICAGO--(BUSINESS WIRE)--May 31, 2008--Amgen (NASDAQ:AMGN) today announced interim results from four of the company's investigational cancer agents. Data presented from trials with recombinant human (rh) Apo2L/TRAIL, AMG 479, AMG 102 and motesanib alone, and in combination with chemotherapy or other targeted agents, are a part of the robust oncology therapeutic development program organized in the pathway areas of apoptosis, growth regulation and angiogenesis. These studies were presented at the 2008 American Society of Clinical Oncology's (ASCO) Annual Meeting in Chicago.

"Cancer is a complex disease which requires innovative therapeutic approaches to attack out-of-control cells," said David Chang, M.D., vice president, Global Oncology Development at Amgen. "While still early, we believe that developing and executing well-designed clinical trials will allow us to explore a range of therapeutic potentials to combat this devastating illness. Our aim is to generate clinical evidence to push the boundaries of conventional cancer treatment by employing novel strategies such as targeting multiple pathways or combining targeted therapies."

Apoptosis: Enhancing Cancer Cell Suicide

Apoptosis, also known as programmed cell death, is a process by which a controlled sequence of biochemical events triggers target cells to commit suicide. This is a normal cellular process by which unwanted or damaged cells are removed from the body. Cancer cells acquire the ability to evade apoptosis, which leads to uncontrolled growth. Amgen is using a pro-apoptotic approach to target the extrinsic cell death pathway, which is mediated through two key death receptors (DR4 and DR5), that may help provide a platform with which traditional cytotoxic and targeted therapies can be combined to treat a variety of cancers.

In a Phase 1b trial, patients with advanced non-small cell lung cancer (NSCLC), received rhApo2L/TRAIL, a pro-apoptotic receptor agonist (PARA) acting through death receptors DR4 and DR5, in combination with the regimen of paclitaxel, carboplatin and bevacizumab (PCB). Interim data from 24 patients found no dose-limiting toxicities in the four dosing cohorts. Four patients experienced a treatment-related serious adverse event. Best overall objective tumor response per the RECIST criteria was 58 percent. This molecule is being developed in collaboration with Genentech. A Phase 2 trial in bevacizumab-eligible and ineligible patients with advanced NSCLC is ongoing.

"The dysregulation of apoptosis is a hallmark of cancer, and targeting pathways with potential pro-apoptotic effects has great potential in the pursuit of new anti-cancer therapies," said David Chang, M.D., vice president, Global Oncology Development at Amgen. "The results of this study are encouraging as we continue to explore this pathway in a broad range of tumor types."

Growth Regulation: Blocking Pathways that Regulate Proliferation of Cancer Cells

There are multiple mechanisms by which cancer cells escape the regulatory processes that control the behavior and fate of normal cells. Restoring the cellular functions that regulate cell growth is of significant interest for the development of anti-cancer therapies. Amgen is developing inhibitors of the insulin-like growth factor-1 receptor (IGF-1R) and hepatocyte growth factor/scatter factor (HGF/SF):c-Met pathways that are potential first-in-class anti-cancer molecules.

At this meeting, Amgen presented data on AMG 479, a fully human monoclonal antibody that binds with a high affinity to IGF-1R. In a Phase 1b study, AMG 479 was combined with either Vectibix(R) (panitumumab) or gemcitabine for the treatment of patients with advanced solid tumors. This study of 21 patients evaluated the safety, pharmacokinetics, and maximum tolerated dose of AMG 479 for each regimen. The study found that AMG 479 could be safely combined with a standard dose of Vectibix or gemcitabine. There was one, grade 3, AMG 479-related, adverse event (high blood sugar) in the AMG 479 and Vectibix arm (n=10). There were no AMG 479 related adverse events greater than grade 3 in the AMG 479 and gemcitabine arm (n=11). A partial response (by WHO criteria) was observed in a patient with metastatic colorectal cancer treated with AMG 479 and Vectibix. Another partial response (also by WHO criteria) was seen in a patient with hormone-resistant prostate cancer treated with AMG 479 and gemcitabine. Stable disease as a best response was noted in an additional six patients in the AMG 479 and Vectibix arm and in an additional seven patients in the AMG 479 and gemcitabine arm.

Data were also presented from a separate trial combining targeted therapies, in which AMG 102, a fully human monoclonal antibody that selectively targets HGF/SF (the only ligand for the c-Met receptor), was combined with bevacizumab or motesanib. In the study, three cohorts of three to six patients with advanced solid tumors received AMG 102 and bevacizumab (n=12) or motesanib (n=2). Results showed that AMG 102 in combination with bevacizumab appeared to be well-tolerated in most patients. One grade 3, adverse event of arthralgia and one, grade 4 event of pulmonary embolism was seen. The most common related adverse events were nausea and fatigue. Among the evaluable patients receiving bevacizumab and AMG 102, most (7) had some tumor shrinkage as the best tumor response.

Additionally, an interim analysis of a Phase 2 study was presented in which AMG 102 was administered as a single agent to 40 patients with recurrent glioblastoma multiforme to assess its safety and efficacy. Recurrent glioblastoma is an aggressive disease for which no standard therapy is available and afflicted patients typically have a poor prognosis. One patient experienced a partial response by Macdonald criteria, and six patients experienced stable disease on therapy with AMG 102. At a data cut-off of January 2008, two patients with recurrent glioblastoma multiforme were still receiving AMG 102. Serious adverse events were reported in eight of 40 patients; only one was reported as a treatment-related serious adverse event. Five patients reported grade 3 or 4 treatment-related adverse events: peripheral edema (n=2), hypophosphatemia (n=3), and deep vein thrombosis (n=1). Grade 1 or 2, treatment-related, adverse events reported in more than two patients included nausea (n=3), diarrhea (n=2), fatigue (n=5), dyspnea (n=2), and dry skin (n=2). There were no treatment-related deaths reported.

Angiogenesis: Preventing Abnormal Formation of New Blood Vessels

Angiogenesis, the process of new blood vessel formation, plays a critical role in many diseases, including cancer. In cancer, tumors grow and metastasize in part by secreting angiogenic substances, such as vascular endothelial growth factor (VEGF) that can induce capillary growth into the tumor.

Amgen presented data from a Phase 1b study evaluating motesanib, a highly selective oral agent that targets VEGF receptors one, two and three (VEGFR 1-3), in combination with gemcitabine and erlotinib in patients with solid tumors (n=57; 48 of which have received one dose of motesanib). The data showed that combination of motesanib with gemcitabine and erlotinib appeared tolerable with little effect on pharmacokinetics. Serious adverse events (grade 3 or higher) included deep vein thrombosis, congestive cardiac failure, cholecystitis, febrile neutropenia, neutropenia and pulmonary embolism. One partial response was seen when motesanib was given 75mg BID in combination with gemcitabine and erlotinib.

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.

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 May 31, 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 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.

CONTACT: Amgen, Thousand Oaks
Christine Regan: 617-359-1324 or 805-447-5476 (media)
Arvind Sood: 805-447-1060 (investors)

SOURCE: Amgen