



Updated Data from Ongoing Phase 3 Trials Support the Continued Study of Vectibix(R) (panitumumab) in Combination with Standard Chemotherapy

June 1, 2008

Phase 2 Data Corroborate the Role of the KRAS Biomarker in Advanced Colorectal Cancer

Abstract Numbers 4064, 4034, 4127

CHICAGO--(BUSINESS WIRE)--June 1, 2008--Amgen (NASDAQ:AMGN) today announced updated interim pooled, blinded, safety results from two Phase 3 trials evaluating Vectibix(R) (panitumumab) in combination with standard chemotherapy in earlier lines of metastatic colorectal cancer (mCRC). Updated data from these trials, as well as the first prospective trial evaluating the impact of the clinical biomarker KRAS on Vectibix efficacy in combination with chemotherapy, were presented at the 2008 American Society of Clinical Oncology's (ASCO) Annual Meeting in Chicago.

"The data being generated from a number of our ongoing trials in various settings of colorectal cancer continue to inform us about the safety of Vectibix in combination with standard chemotherapy," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "Our data regarding the importance of KRAS mutation status emphasize the significance of this biomarker in developing individualized therapy for colorectal cancer."

PRIME (203) Study

The "PRIME" or 20050203 study is a global, Phase 3 trial investigating Vectibix in combination with FOLFOX chemotherapy as first-line treatment for mCRC among wild-type KRAS and all randomized patients. Final enrollment was completed in February 2008 with a total of 1,183 patients.

Pooled safety data from a planned interim analysis, conducted by an independent Data Monitoring Committee (DMC), of 903 patients (455 Vectibix plus FOLFOX; 448 FOLFOX only), of which 99 percent received at least one cycle of therapy, showed the following pooled grade 3/4 adverse events: neutropenia (28 percent), diarrhea (11 percent), fatigue (4 percent), nausea (3 percent), dehydration (3 percent) and hypomagnesaemia, pulmonary embolism, febrile neutropenia and deep vein thrombosis (2 percent, respectively). Fifty-six percent of the pooled patient population had skin and subcutaneous tissue system organ class (SOC) events of any grade; 10 percent grade 3 and less than one percent grade 4. Based upon this interim safety analysis, the DMC recommended that the PRIME study continue per protocol.

Patients enrolled in this study were randomized to receive either 6.0 mg/kg of Vectibix and FOLFOX once every two weeks (Q2W) or FOLFOX alone Q2W. The primary endpoint is progression-free survival (PFS). Other endpoints include overall survival, objective response rate, time to progression, duration of response and safety.

All study endpoints will be investigated by patients' KRAS mutational status in both treatment arms as a biomarker for Vectibix activity in combination with FOLFOX chemotherapy as first-line treatment for mCRC.

181 Study

The 20050181 ("181") study is a global, Phase 3 trial investigating Vectibix in combination with FOLFIRI chemotherapy as second-line treatment for patients with mCRC assessed according to KRAS mutational status. The 181 study final enrollment was completed in March 2008 with a total of 1,187 patients.

Pooled safety data from a planned interim analysis, conducted by the independent DMC, of 1,097 patients (548 Vectibix plus FOLFIRI; 549 FOLFIRI only), of which 99.6 percent received at least one cycle of therapy, showed the following pooled grade 3/4 adverse events: neutropenia (17 percent), diarrhea (10 percent), fatigue (5 percent), nausea, dehydration, pulmonary embolism, febrile neutropenia (2 percent, respectively), and hypomagnesaemia and deep vein thrombosis (1 percent, respectively). Sixty-three percent of the pooled patient population had skin and subcutaneous tissue SOC events of any grade; 15 percent grade 3 and less than one percent grade four. Based upon this interim safety analysis, the DMC recommended that the 181 study continue per protocol.

Patients were randomized to receive either 6.0 mg/kg of Vectibix and FOLFIRI Q2W or FOLFIRI Q2W alone. The co-primary endpoints are progression-free survival and overall survival. Other endpoints include objective response rate, time to progression, duration of response and safety.

All study endpoints will be investigated by patients' KRAS mutational status in both treatment arms as a biomarker for Vectibix activity in combination with FOLFIRI chemotherapy as second-line treatment for mCRC.

PRECEPT

The single-arm PRECEPT study (n=109) was designed to prospectively evaluate the efficacy of Vectibix when combined with the chemotherapy regimen FOLFIRI, according to KRAS status, in patients with metastatic disease which had progressed following first-line treatment with an oxaliplatin-based chemotherapy regimen plus bevacizumab.

Data from this interim efficacy analysis (n=64 wild-type KRAS, n=45 mutant KRAS) showed that patients with wild-type KRAS had longer PFS (median: 26 weeks wild-type versus 16 weeks mutant KRAS) and time to treatment failure (median: 20 weeks wild-type versus 15 weeks mutant KRAS). Overall response rates were similar in this interim analysis. In line with other EGFR-inhibitor class data in combination with chemotherapy, the addition of Vectibix to FOLFIRI was tolerable. Vectibix-related serious adverse events (grade 3 or higher) were observed in 15 patients, or 13 percent of the 115 patients included in the safety analysis. The most frequently reported serious adverse events were neutropenia (23 percent), skin-related toxicity (19 percent) and diarrhea (13 percent).

"These data are the first to measure the potential impact of KRAS status in combination treatment with Vectibix and chemotherapy, and add to the growing body of evidence that help validate KRAS as a potential patient selection biomarker for anti-EGFR therapy," said Allen Cohn, M.D., Rocky

Mountain Cancer Center, U.S. Oncology, Denver, Colorado. "KRAS mutational status ranks among one of the most important scientific advances in colorectal cancer and has the potential to redefine how these patients are currently treated."

About Vectibix

Vectibix is the EGFR-inhibitor of choice in the treatment of advanced colorectal cancer patients who have failed standard chemotherapy due to its demonstrated efficacy, safety and convenient Q2W dosing schedule.

In the United States (U.S.), Vectibix is indicated for the treatment of patients with EGFR-expressing mCRC after disease progression on, or following fluoropyrimidine-, oxaliplatin- and irinotecan-containing chemotherapy regimens. The effectiveness of Vectibix for the treatment of EGFR-expressing, metastatic colorectal carcinoma is based on progression-free survival. Currently no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.

In the European Union (EU), Vectibix is approved as monotherapy for the treatment of patients with EGFR-expressing mCRC with non-mutated (wild-type) KRAS genes after failure of standard chemotherapy regimens.

Important Product Safety Information

Dermatologic toxicities, related to Vectibix blockade of EGF binding and subsequent inhibition of EGF receptor-mediated signaling pathways, included but were not limited to dermatitis acneiform, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures. Dermatologic toxicities were reported in 89 percent of patients treated with Vectibix and were severe in 12 percent of patients. Severe dermatologic toxicities were complicated by infection, including sepsis, septic death, and abscesses requiring incisions and drainage. Vectibix may need to be withheld or discontinued for severe dermatologic toxicities.

Severe infusion reactions occurred with Vectibix in approximately one percent of patients. Severe infusion reactions were identified as anaphylactic reactions, bronchospasm, fever, chills and hypotension. Although fatal infusion reactions have not been reported with Vectibix, they have occurred with other monoclonal antibody products. Severe infusion reactions require stopping the infusion and possibly permanently discontinuing Vectibix, depending on the severity and/or persistence of the reaction.

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 June 1, 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 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 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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SOURCE: Amgen