Amgen Announces Top-Line Results of Vectibix® (panitumumab) Phase 3 Head-to-Head Study Against Erbitux® (cetuximab) in Metastatic Colorectal Cancer

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Study Meets Primary Endpoint of Non-Inferiority in Monotherapy Setting

THOUSAND OAKS, Calif., May 7, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the Phase 3 head-to-head ASPECCT ('763) trial evaluating Vectibix® (panitumumab) versus Erbitux® (cetuximab) as a single agent for the treatment of chemorefractory metastatic colorectal cancer (mCRC) in patients with wild-type *KRAS* tumors (n=1,010) met its primary endpoint of non-inferiority for overall survival. The estimated overall survival hazard ratio (Vectibix/Erbitux) was 0.966 (95 percent CI: 0.839, 1.113) favoring the Vectibix arm.

Overall, the relative adverse event profiles were as anticipated for each of the anti-EGFR therapies studied, including known events such as rash, diarrhea and hypomagnesemia.

Colorectal cancer is the third most common cancer found in both men and women in the U.S., and is the second leading cause of cancer deaths.[1, 2] Approximately 1.2 million cases of colorectal cancer are expected to occur globally.[3]

Detailed safety and efficacy data will be submitted for presentation at an upcoming medical meeting later this year.

ASPECCT ('763) Trial Design

ASPECCT is a global, randomized, parallel assignment, open-label, Phase 3 non-inferiority trial designed to compare the effect of Vectibix versus Erbitux on overall survival for monotherapy treatment of chemorefractory mCRC in 1,010 patients with wild-type *KRAS* tumors (primary endpoint). Secondary endpoints included safety, patient reported outcomes, progression-free survival, time to response, time to treatment failure and duration of response.

Patients were randomized in a 1:1 ratio to receive 6 mg/kg of intravenous Vectibix every 14 days or 400 mg/m^2 of an initial dose of intravenous Erbitux followed by 250 mg/m^2 of intravenous Erbitux every seven days.

In Europe, the ASPECCT trial is a Specific Obligation for Vectibix as part of the European Medicine Agency's (EMA) conditional marketing authorization.

About Vectibix

Vectibix is the first fully human anti-epidermal growth factor receptor (EGFR) antibody approved by the U.S. Food and Drug Administration (FDA) for the treatment of metastatic colorectal cancer (mCRC). Vectibix was approved in the U.S. in September 2006 as a single agent for the treatment of metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine, oxaliplatin and irinotecan chemotherapy regimens. Approval is based on progression-free survival; no data demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.

Important U.S. Product Information

Vectibix is indicated as a single agent for the treatment of EGFR-expressing, mCRC with disease progression on or following fluoropyrimidine-, oxaliplatin- and irinotecan-containing chemotherapy regimens. The effectiveness of Vectibix as a single agent for the treatment of EGFR-expressing mCRC is based on progression-free survival. Currently, no data demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.

Vectibix is not indicated for the treatment of patients with *KRAS* mutation-positive mCRC or for whom *KRAS* mCRC status is unknown. Retrospective subset analyses of mCRC trials have not shown a treatment benefit for Vectibix in patients whose tumors had *KRAS* mutations in codon 12 or 13.

WARNING: DERMATOLOGIC TOXICITY and INFUSION REACTIONS

Dermatologic Toxicity: Dermatologic toxicities occurred in 89 percent of patients and were severe (NCI-CTC grade 3 or higher) in 12 percent of patients receiving Vectibix monotherapy. [See Dosage and Administration (2.1), Warnings and Precautions (5.1), and Adverse Reactions (6.1)].

Infusion Reactions: Severe infusion reactions occurred in approximately one percent of patients. Fatal infusion reactions occurred in postmarketing experience. [See Dosage and Administration (2.1), Warnings and Precautions (5.2), and Adverse Reactions (6.1, 6.3)].

The most common adverse reactions (≥ 20 percent) of Vectibix are skin rash with variable presentations, hypomagnesemia, paronychia, fatigue, abdominal pain, nausea, diarrhea, including diarrhea resulting in dehydration.

The most serious adverse reactions of Vectibix are pulmonary fibrosis, pulmonary embolism, severe dermatologic toxicity complicated by infectious sequelae and septic death, infusion reactions, abdominal pain, hypomagnesemia, nausea, vomiting, and constipation.

Important European Product Information

- Vectibix has been approved in the European Union for the treatment of patients with wild-type *KRAS* metastatic colorectal cancer (mCRC):
  - in first-line in combination with FOLFOX
  - in second-line in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan)

    - as monotherapy after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.
- Vectibix is contraindicated in patients with a history of severe or life-threatening hypersensitivity reactions to the product and in patients with interstitial pneumonitis or pulmonary fibrosis. Vectibix should not be administered in combination with oxaliplatin-containing chemotherapy to mCRC patients with mutant *KRAS* tumors or for whom *KRAS* tumor status is unknown.
- Adverse events of special importance associated with Vectibix and/or EGFR monoclonal antibody therapies include dermatologic-related reactions, pulmonary complications, electrolyte disturbances, infusion-related reactions (including rare reports with fatal outcome) and ocular toxicities. Acute renal failure has been observed in patients who develop severe diarrhea and dehydration. These events should be monitored carefully, see Summary of Product Characteristics for information on appropriate management of these adverse events.
- Vectibix should not be used in combination with IFL chemotherapy or in combination with bevacizumab containing chemotherapy. For patients with ECOG 2 performance status, assessment of benefit-risk is recommended prior to initiation of Vectibix in combination with chemotherapy for treatment of mCRC.

To see the full Vectibix Safety Information, visit www.vectibix.com.

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 people around the world in the fight against serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

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 any subsequent 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 7, 2013 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. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. 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 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.

Erbitux® is a registered trademark of ImClone LLC.

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[1]Cancer Facts and Figures 2013. American Cancer Society website. http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-036845.pdf. Accessed March 25, 2013.

[2]Colorectal Cancer Prevention (PDQ®). National Cancer Institute. Accessed March 25, 2013. http://www.cancer.gov/cancertopics/pdq/prevention/colorectal/HealthProfessional/page3.

[3]Jemal. Global Cancer Statistics. *CA Cancer J Clin.* 2011;61:69-90.

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