Amgen Highlights Data To Be Presented At 2013 European Cancer Congress

September 12, 2013

THOUSAND OAKS, Calif., Sept. 12, 2013 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that it will present new data from studies of marketed and pipeline products at the 17th ECCO - 38th ESMO - 32nd ESTRO European Cancer Congress happening Sept. 27 to Oct. 1 in Amsterdam.

"Amgen's continued focus on growth through innovation is highlighted by the data that we are presenting at the European Cancer Congress this year," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We are successfully advancing our pipeline, while using cutting-edge science to better understand each cancer's unique fingerprint and provide individualized care for patients."

Abstracts are available on the European Cancer Congress website at http://eccamsterdam2013.ecco-org.eu/.

Data presented on talimogene laherparepvec will include:

- **Secondary Endpoints from OPTiM: A Multicenter, Randomized Phase 3 Trial of Talimogene Laherparepvec vs. GM-CSF for the Treatment of Unresected Stage IIIB/C and IV Melanoma**
  Abstract 3733 / P479, Poster Session, Monday, Sept. 30, 9:30 a.m. - 12:00 p.m. CEST (Hall 4)

Data presented on trebananib will include:

- **A Phase 3, Randomized, Double-Blind Trial of Weekly Paclitaxel Plus the Angiopoietin 1 and 2 Inhibitor, Trebananib, or Placebo in Women With Recurrent Ovarian Cancer: TRINOVA-1**
  Abstract 41, Late Breaking Abstract, Proffered Papers Session, Tuesday, Oct. 1, 10:53 - 11:05 a.m. CEST (Hall 7.2)

Data presented on Vectibix® (panitumumab) will include:

- **ASPECCT: A Randomized, Multicenter, Open-Label, Phase 3 Study of Panitumumab vs. Cetuximab for Previously Treated Wild-Type *KRAS* Metastatic Colorectal Cancer**
  Abstract 18, Late Breaking Abstract, Proffered Papers Session, Saturday, Sept. 28, 1:47 - 2:10 p.m. CEST (RAI Auditorium)
- **Tumor Genetic Analysis of PRIME: *KRAS*, *NRAS*, and *BRAF* Mutations as Predictive Biomarkers in Patients with Metastatic Colorectal Cancer Receiving First-Line Treatment With Panitumumab Plus FOLFOX4**
  Abstract 2275 / P157, Poster Session, Sunday, Sept. 29, 2:00 - 4:30 p.m. CEST (Hall 4)
- **Updated Overall Survival Analysis of Novel Predictive *KRAS/NRAS* Mutations Beyond *KRAS* Exon 2 in PEAK: A First-Line Phase 2 Study of FOLFOX6 plus Panitumumab or Bevacizumab in Metastatic Colorectal Cancer**
  Abstract 2262 / P144, Poster Session, Sunday, Sept. 29, 2:00 - 4:30 p.m. CEST (Hall 4)

About Talimogene Laherparepvec
Talimogene laherparepvec is an investigational oncolytic immunotherapy designed to selectively replicate in tumor tissue. Talimogene laherparepvec is injected directly into tumor tissue and then replicates until the membrane of the cancer cells rupture, thereby destroying the cells, in a process known as cell lysis. The virus that was contained in these cells is then released locally in the tumor tissue along with potential tumor antigens and GM-CSF, a white blood cell growth factor that the virus is engineered to express. This is intended to lead to the activation of a systemic immune response to kill tumor cells throughout the body.

About Trebananib
Trebananib is an investigational peptibody designed to inhibit the angiopoietin axis. The angiopoietin axis is involved in angiogenesis, a process used by the body to grow new blood vessels, which is also involved in the pathogenesis of several diseases including cancer. Trebananib is designed to bind to both angiopoietin-1 and -2 (Ang1 and Ang2), and is intended to inhibit their interaction with the Tie2 receptor.[1,2,3] Ang1 and Ang2 each mediate separate actions upon binding with Tie2.[4,5] Ang1 impacts vessel quality while Ang2 influences vessel quantity. The angiopoietins are also involved in lymphangiogenesis, the formation of new lymphatic vessels, which plays a key role in tumor metastasis.[6]

About Vectibix
Vectibix is the first fully human anti-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 monotherapy 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 as a single agent for the treatment of EGFR-expressing mCRC is based on progression-free survival. Currently no data are available that 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. Vectibix in combination with oxaliplatin-based chemotherapy is not indicated for the treatment of patients with *RAS* (*KRAS* or *NRAS*) mutation-positive mCRC or for whom *RAS* status is unknown.

In December 2007, the European Medicine Agency (EMA) granted a conditional marketing authorization for Vectibix as a monotherapy for the treatment of patients with EGFR-expressing mCRC with non-mutated (wild-type) *KRAS* after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-

containing chemotherapy regimens. In July 2013, the indication was updated to the following:

Vectibix is indicated for the treatment of adult patients with wild-type *RAS* 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 approved in over 50 countries worldwide.

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 metastatic colorectal cancer trials have not shown a treatment benefit for Vectibix in patients whose tumors had KRAS mutations in codon 12 or 13. Vectibix in combination with oxaliplatin-based chemotherapy is not indicated for the treatment of patients with *RAS* (*KRAS* or *NRAS*) mutation-positive mCRC or for whom *RAS* status is unknown.

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 events of Vectibix are skin rash with variable presentations, hypomagnesemia, paronychia, fatigue, abdominal pain, nausea and 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 Safety Information

For full prescribing information please see the Summary of Product Characteristics.

Vectibix is indicated for the treatment of adult patients with wild-type RAS 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.

The combination of Vectibix with oxaliplatin-containing chemotherapy is contraindicated for patients with mutant *RAS* mCRC or for whom *RAS* mCRC status is unknown

Other common adverse events of special importance associated with Vectibix and/or EGFR monoclonal antibody therapies include dermatologic-related reactions, pulmonary complications, electrolyte disturbances and infusion-related reactions (including rare reports with fatal outcome). These events should be monitored carefully, see Summary of Product Characteristics for information on appropriate management of these adverse events. Acute renal failure has been observed in patients who develop severe diarrhoea and dehydration.

Vectibix should not be used in combination with IFL [bolus 5-fluorouracil (500 mg/m2), leucovorin (20 mg/m2) and irinotecan (125 mg/m2)] or in combination with bevacizumab containing chemotherapy.

About Amgen
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

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 Sept. 12, 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 product 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 payers, 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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