



Amgen Highlights Data To Be Presented At American Society of Clinical Oncology Annual Meeting

May 15, 2013

THOUSAND OAKS, Calif., May 15, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present data from several studies of both pipeline and marketed products at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting from May 31 to June 4 in Chicago.

"The data that we are presenting at ASCO demonstrate great progress with our effort to develop treatments that will help patients with advanced cancers," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "As a company rooted in biology, we are in a strong position to develop innovative therapies that fight cancer through new pathways such as immunotherapy and to leverage biomarkers to advance personalized medicine."

Meeting delegates who visit Amgen's booth will also have the opportunity to learn more about Amgen's legacy of manufacturing expertise – from research and development to delivery of complex biological therapies.

Abstracts are currently available on the ASCO website at <http://abstract.asco.org/>.

ABSTRACTS OF INTEREST INCLUDE:

Talimogene Laherparepvec

The results of the primary analysis of the pivotal trial of talimogene laherparepvec, an investigational oncolytic immunotherapy for the treatment of melanoma, including interim overall survival data, will be presented.

- **OPTiM: A Randomized Phase 3 Trial of Talimogene Laherparepvec (T-VEC) versus Subcutaneous (SC) Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) for the Treatment (tx) of Unresected Stage IIIB/C and IV Melanoma**

Abstract No. LBA9008, Oral Presentation, Saturday, June 1, 3:45 p.m. CDT, S406

Blinatumomab

Results from a Phase 1 study in pediatric patients with acute lymphoblastic leukemia (ALL) will be presented for blinatumomab, the first of a new investigational class of agents designed to harness the body's cytotoxic T cells to kill cancer cells.

- **Cytological and Molecular Remissions With Blinatumomab Treatment in Second or Later Bone Marrow Relapse in Pediatric Acute Lymphoblastic Leukemia (ALL)**

Abstract No. 10007, Oral Presentation, Sunday, June 2, 10:30 a.m. CDT, S504

Vectibix® (panitumumab)

Three new analyses of trials studying Vectibix in combination with FOLFOX, an oxaliplatin-based chemotherapy, as a first-line treatment for metastatic colorectal cancer (mCRC) will be presented. Presentations include two analyses of the Phase 3 PRIME ('203) trial: an updated overall survival analysis and an analysis of the treatment effect by *RAS/RAF* status, respectively. The Phase 3 PRIME ('203) trial evaluated Vectibix plus FOLFOX versus FOLFOX alone in patients with wild-type *KRAS* mCRC. An analysis by *RAS* status of the Phase 2 PEAK ('509) trial comparing the efficacy of Vectibix in combination with FOLFOX to the efficacy of bevacizumab in combination with FOLFOX in patients with wild-type *KRAS* mCRC will also be presented.

- **Overall Survival (OS) Analysis from PRIME: Randomized Phase 3 Study of panitumumab (pmab) with FOLFOX4 for First-line Metastatic Colorectal Cancer (mCRC)**
Abstract No. 3620, Poster, Sunday, June 2, 8:00 a.m. CDT, S Hall A2
- **Analysis of *KRAS/NRAS* Mutations in PEAK: A Randomized Phase II Study of FOLFOX6 plus Panitumumab (pmab) or Bevacizumab (bev) as First-line Treatment (tx) for Wild-type (WT) *KRAS* (exon 2) Metastatic Colorectal Cancer (mCRC)**
Abstract No. 3631, Poster, Sunday, June 2, 8:00 a.m. CDT, S Hall A2
- **Analysis of *KRAS/NRAS* and *BRAF* Mutations in the Phase 3 PRIME Study of Panitumumab (pmab) + FOLFOX vs FOLFOX as First-line Treatment (tx) for Metastatic Colorectal Cancer (mCRC)**
Abstract No. 3511, Poster Discussion, Tuesday, June 4, 8:00 a.m. CDT, S405

About Talimogene Laherparepvec

Talimogene laherparepvec is an investigational oncolytic immunotherapy derived from herpes simplex virus type-1 designed to selectively replicate within cancer cells and to produce GM-CSF to enhance systemic antitumor immune responses. Talimogene laherparepvec is injected directly into tumor tissue and replicates until the membranes of the cancer cells rupture, thereby destroying them in a process known as oncolysis. The virus contained in these cells as well as potential tumor antigens are then released locally along with GM-CSF, a white blood cell growth factor that the virus is engineered to express. This is intended to activate antigen presenting cells and elicit a systemic immune response to kill tumor cells throughout the body.

About Blinatumomab

Blinatumomab is an investigational bi-specific T cell engager (BiTE[®]) antibody designed to direct the body's cytotoxic T cells against target cells expressing CD19, a protein found on the surface of B-cell derived leukemias and lymphomas. The modified antibodies are designed to engage two

different targets simultaneously, thereby juxtaposing T cells with cancer cells. Blinatumomab is the first of the BiTE antibodies, and Amgen has received orphan drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of ALL, chronic lymphocytic leukemia (CLL), hairy cell leukemia, prolymphocytic leukemia and indolent B cell lymphoma and from the European Medicines Agency for the treatment of indolent B cell lymphoma, ALL, CLL and mantle cell leukemia (MCL).

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 United States 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 metastatic colorectal cancer 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 ($\geq 20\%$) 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.

To see the full Vectibix Prescribing 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 15, 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.

CONTACT: Amgen, Thousand Oaks
Ashleigh Koss, 805-313-6151 (media)
Arvind Sood, 805-447-1060 (investors)

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