Amgen and Onyx Data at ASCO 2014 Highlight Oncology Pipeline and Portfolio

May 27, 2014

New Data Reinforces Commitment to Personalized Medicine and Highlights Advances in Immunotherapy Platform

THOUSAND OAKS, Calif. and SOUTH SAN FRANCISCO, Calif., May 27, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and its subsidiary Onyx Pharmaceuticals, Inc., today announced data from several studies of both pipeline and marketed products will be presented at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) being held May 30-June 3 in Chicago. The research that will be presented demonstrates Amgen's and Onyx's continued progress in developing treatments for patients with difficult-to-treat cancers, as well as investigating new uses and areas of interest for their current cancer care treatments.

"The data presented at ASCO this year is a testament to our focus on addressing unmet needs and the strategic acquisitions that we have made, such as Onyx, to further our leadership in oncology," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Amgen and Onyx continue to be on the cutting edge of research and are constantly looking for innovative approaches to tackle some of the toughest cancers."

During the meeting, Amgen and Onyx will present results from more than 45 studies in 17 different cancers, including six oral presentations and 25 posters across 11 oncology molecules. Abstracts are currently available on the ASCO website at http://abstract.asco.org/.

Amgen Data Includes:

Blinatumomab (AMG 103)

Amgen will present results from the following pivotal Phase 2 study assessing blinatumomab, a bispecific T cell engager (BiTE®) antibody, in patients with acute lymphoblastic leukemia (ALL).

- **Confirmatory open-label, single-arm, multicenter Phase 2 study of the BiTE® antibody blinatumomab in patients with relapsed/refractory B-precursor acute lymphoblastic leukemia**
  Abstract No. 7005, Oral Abstract Session, Tuesday, June 3, 9:45 a.m. to 12:45 p.m. CT, E354a

Talimogene Laherparepvec

New data will be presented in patients with metastatic melanoma. Talimogene laherparepvec data to be presented at ASCO includes monotherapy data from the Phase 3 OPTiM trial as well as data on the combination of talimogene laherparepvec with another immunotherapy.

- **Primary analysis of a Phase 1b multicenter trial to evaluate safety and efficacy of talimogene laherparepvec (T-VEC) and ipilimumab (ipi) in previously untreated, unresected, stage IIIB-IV melanoma**
  Abstract No. 9029, Poster Highlights Session, Monday, June 2, 8 a.m. to 11 a.m. CT, E354b and 11:30 a.m. to 12:45 p.m. CT, E Arie Crown Theater
- **Patterns of durable response with intralesional talimogene laherparepvec (T-VEC): Results from a Phase 3 trial in patients with stage IIIB-IV melanoma**
  Abstract No. 9026, Poster Highlights Session, Monday, June 2, 8 a.m. to 11 a.m. CT, E354b and 11:30 a.m. to 12:45 p.m. CT, E Arie Crown Theater
- **Primary overall survival (OS) from 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. 9008a, Oral Abstract Session, Monday, June 2, 3 p.m. to 6 p.m. CT, E Arie Crown Theater

Vectibix® (panitumumab)

Two studies to be presented at ASCO will provide more detailed information about predictive biomarkers in patients with metastatic colorectal cancer (mCRC). On May 23, 2014, the U.S. Food and Drug Administration (FDA) approved Vectibix plus FOLFOX chemotherapy as a first-line treatment for patients with wild-type *KRAS* mCRC. With this approval, Vectibix became the first and only biologic therapy indicated for use with FOLFOX, one of the most commonly used chemotherapy regimens in the first-line treatment of wild-type *KRAS* mCRC patients.

- **Survival outcomes in the PRIME study for patients with RAS/BRAF wild-type (WT) metastatic colorectal cancer (mCRC), by baseline Eastern Cooperative Oncology Group (ECOG) performance status**
  Abstract No. 3557, General Poster Session, Saturday, May 31, 8 a.m. to 11:45 a.m. CT, S Hall A2
- **Extended RAS analysis and subsequent anti-EGFR and anti-VEGF treatment (tx) in PEAK: a 1st-line Phase 2 study of FOLFOX6 + panitumumab (pmab) or bevacizumab (bev) in metastatic colorectal cancer**
  Abstract No. 3629, General Poster Session, Saturday, May 31, 8 a.m. to 11:45 a.m. CT, S Hall A2

XGEVA® (denosumab)

Amgen will present data from imaging studies that reveal early, sustained and progressive activity in giant cell tumor of bone (GCTB) and additional data regarding the prevention of skeletal related events (SREs) in patients with bone metastases.

- **Response to treatment with denosumab in patients with giant cell tumor of bone (GCTB): FDG PET results from two Phase 2 trials**

Abstract No. 10505, Oral Abstract Session, Sunday, June 1, 8 a.m. to 11 a.m. CT, S406

- **Effect of denosumab versus zoledronic acid (ZA) at preventing skeletal-related events (SREs) in patients with metastatic bone disease: subgroup analyses by baseline characteristics**
  Abstract No. 9501, Oral Abstract Session, Monday, June 2, 3 p.m. to 6 p.m. CT, E253
- **Symptomatic skeletal events (SSE) in patients with advanced prostate cancer: results from a Phase 3 trial of denosumab for the prevention of skeletal-related events**
  Abstract No. 5075, General Poster Session, Monday, June 2, 1:15 p.m. to 5 p.m. CT, S Hall A2

Onyx Data Includes:

Kyprolis® (carfilzomib)

New data will be presented from the CHAMPION-1 study evaluating the safety and efficacy of once-weekly carfilzomib with dexamethasone for patients with relapsed or refractory multiple myeloma.

- **Results of the dose-escalation portion of a Phase 1/2 study (CHAMPION-1) investigating weekly carfilzomib in combination with dexamethasone for patients with relapsed or refractory multiple myeloma**
  Abstract No. 8594, General Poster Session, Monday, June 2, 1:15 p.m. to 5 p.m. CT, S Hall A2

Amgen Post-ASCO Summary Webcast

Amgen will hold a post-ASCO summary webcast on Tuesday, June 3, 2014, at 1 p.m. PT. Sean E. Harper, M.D., executive vice president of Research and Development at Amgen, along with members of Amgen's clinical development team will participate to discuss data presented at ASCO and Amgen's broader oncology portfolio of products.

Live audio of the conference call will be simultaneously broadcast over the Internet and will be available to members of the news media, investors and the general public.

The webcast, as with other selected presentations regarding developments in Amgen's business given by management at certain investor and medical conferences, can be found on Amgen's website, www.amgen.com, under Investors. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

About Blinatumomab (AMG 103)

Blinatumomab (AMG 103) is a bispecific T cell engager (BiTE®) antibody and is currently being investigated for the treatment of ALL and non-Hodgkin's lymphoma. BiTE antibodies are designed to engage two different targets simultaneously. This dual binding ability allows BiTE antibodies to act as bridges between T cells (a type of white blood cell capable of killing other cells perceived as threats) and tumor cells. BiTE antibodies place the T cells within reach to inject toxins into the tumor cell. Blinatumomab is designed to direct the T cells to target cells expressing CD19, a protein found on the surface of most B cell-derived leukemias and lymphomas. Blinatumomab has received orphan drug designation from the FDA.

About Talimogene Laherparepvec

Talimogene laherparepvec is an investigational oncolytic immunotherapy designed to selectively replicate in tumors (but not normal tissue) and to initiate an immune response to target cancer cells that have metastasized. Talimogene laherparepvec was designed to work in two important and complementary ways. First, it is injected directly into tumors where it replicates inside the tumor's cells causing the cell to rupture and die in a process called lysis. The rupture of the cancer cells can release tumor-derived antigens, along with GM-CSF, that can stimulate a system-wide immune response where white blood cells are able to seek out and target cancer that has spread throughout the body.

About Vectibix® (panitumumab)

Vectibix is the first fully human anti-EGFR antibody approved by the FDA for the treatment of 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 after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.

In May 2014, the FDA approved Vectibix for use in combination with FOLFOX, as first-line treatment in patients with wild-type *KRAS* (exon 2) mCRC. With this approval, Vectibix became the first and only biologic therapy indicated for use with FOLFOX, one of the most commonly used chemotherapy regimens, in the first-line treatment of mCRC for patients with wild-type KRAS mCRC.

Important U.S. Product Information

Vectibix is indicated for the treatment of patients with wild-type *KRAS* (exon 2 in codons 12 or 13) mCRC as determined by an FDA-approved test for this use:

- As first-line therapy in combination with FOLFOX
- As monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy

Vectibix is not indicated for the treatment of patients with *KRAS*-mutant mCRC or for whom *KRAS* mutation status is unknown.

WARNING: DERMATOLOGIC TOXICITY

Dermatologic Toxicity: Dermatologic toxicities occurred in 90 percent of patients and were severe (NCI-CTC grade 3 or higher) in 15 percent of patients receiving Vectibix monotherapy. [See Dosage and Administration (2.1), Warnings and Precautions (5.1), and Adverse Reactions (6.1)].

Determination of *KRAS* mutational status in colorectal tumors using an FDA-approved test indicated for this use is necessary for selection of patients for treatment with Vectibix. Patients with *KRAS*-mutant mCRC tumors receiving Vectibix in combination with FOLFOX experienced shorter OS compared to FOLFOX alone.

Progressively decreasing serum magnesium levels leading to severe (Grade 3-4) hypomagnesemia occurred in up to 7% of patients across clinical trials. Monitor patients for hypomagnesemia and hypocalcemia prior to initiating Vectibix treatment, periodically during Vectibix treatment, and for up to 8 weeks after the completion of treatment.

In a clinical trial, 4% of patients experienced infusion reactions and 1% of patients experienced severe infusion reactions (NCI-CTC grade 3-4).

Severe diarrhea and dehydration, leading to acute renal failure and other complications, have been observed in patients treated with Vectibix in combination with chemotherapy.

Fatal and non-fatal cases of interstitial lung disease (ILD) (1%) and pulmonary fibrosis have been observed in patients treated with Vectibix. Pulmonary fibrosis occurred in less than 1% (2/1467) of patients enrolled in clinical studies of Vectibix. In the event of acute onset or worsening of pulmonary symptoms, interrupt Vectibix therapy. Discontinue Vectibix therapy if ILD is confirmed.

The most common adverse reactions of Vectibix are skin rash with variable presentations, paronychia, fatigue, nausea and diarrhea. The most frequently reported serious, adverse reactions of Vectibix are general physical health deterioration, and intestinal obstruction.

The most commonly reported adverse reactions (≥ 20%) in patients with wild-type KRAS mCRC receiving Vectibix (6 mg/kg every 2 weeks) and FOLFOX therapy (N = 322) in Study 3 were diarrhea, stomatitis, mucosal inflammation, asthenia, paronychia, anorexia, hypomagnesemia, hypokalemia, rash, acneiform dermatitis, pruritus, and dry skin. Serious adverse reactions (≥ 2% difference between treatment arms) in Vectibix-treated patients with wild-type KRAS mCRC were diarrhea and dehydration.

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

About XGEVA® (denosumab)
XGEVA was approved by the FDA for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors in 2010. XGEVA is not indicated for the prevention of SREs in patients with multiple myeloma. In clinical trials, XGEVA demonstrated a clinically meaningful improvement compared to the previous standard of care in preventing these bone complications.

In 2013, XGEVA was approved by the FDA as the first and only treatment for adults and skeletally mature adolescents with Giant Cell Tumor of Bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity.

Denosumab is also marketed as Prolia® in other indications.

Important U.S. Product Information for XGEVA
Hypocalcemia
Pre-existing hypocalcemia must be corrected prior to initiating therapy with XGEVA. XGEVA can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Monitor calcium levels and administer calcium, magnesium, and vitamin D as necessary. Monitor levels more frequently when XGEVA is administered with other drugs that can also lower calcium levels. Advise patients to contact a healthcare professional for symptoms of hypocalcemia.

Hypersensitivity
XGEVA is contraindicated in patients with known clinically significant hypersensitivity to XGEVA, including anaphylaxis that has been reported with use of XGEVA. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue XGEVA therapy permanently.

Drug Products with Same Active Ingredient
Patients receiving XGEVA should not take Prolia® (denosumab).

Osteonecrosis of the Jaw
Osteonecrosis of the jaw (ONJ) can occur in patients receiving XGEVA. Patients who are suspected of having or who develop ONJ while on XGEVA should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition. In clinical trials in patients with osseous metastasis, the incidence of ONJ was higher with longer duration of exposure.

Atypical Subtrochanteric and Diaphyseal Femoral Fracture
Atypical femoral fracture has been reported with XGEVA. These fractures can occur anywhere in the femoral shaft from just below the lesser trochanter to above the supracondylar flare and are transverse or short oblique in orientation without evidence of comminution.

Atypical femoral fractures most commonly occur with minimal or no trauma to the affected area. During XGEVA treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Patient presenting with an atypical femur fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of XGEVA therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Embryo-Fetal Toxicity
XGEVA can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use highly effective contraception during therapy, and for at least 5 months after the last dose of XGEVA.

Adverse Reactions
The most common adverse reactions in patients receiving XGEVA with bone metastasis from solid tumors were fatigue/asthenia, hypophosphatemia, and nausea. The most common serious adverse reaction was dyspnea.

To see the full XGEVA Safety Information, visit www.xgeva.com.

About Kyprolis® (carfilzomib) for Injection
On July 20, 2012, the FDA granted accelerated approval of Kyprolis for Injection for the treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent (IMiD), and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval was based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.

Important U.S. Product Information for Kyprolis for Injection
Safety data have been evaluated in 526 patients with relapsed and/or refractory multiple myeloma who received single-agent Kyprolis. There were 37 deaths in the Phase 2 studies, or 7 percent of patients. The most common causes of death, other than disease progression, were cardiac (5 patients), end-organ failure (4 patients), and infection (4 patients). Important warnings and precautions include cardiac arrest, congestive heart failure, myocardial ischemia; pulmonary hypertension, pulmonary complications, infusion reactions, tumor lysis syndrome, thrombocytopenia, hepatic toxicity and embryo-fetal toxicity.

Death due to cardiac arrest has occurred within a day of Kyprolis administration. Patients with New York Heart Association Class III and IV heart failure, myocardial infarction in the preceding 6 months, and conduction abnormalities uncontrolled by medications were not eligible for the clinical trials. These patients may be at greater risk for cardiac complications.

Pulmonary arterial hypertension (PAH) was reported in 2 percent of patients treated with Kyprolis and was Grade 3 or greater in less than 1 percent of patients. Dyspnea was reported in 35 percent of patients enrolled in clinical trials. Grade 3 dyspnea occurred in 5 percent; no Grade 4 events, and 1 death (Grade 5) was reported.

Infusion reactions, characterized by a spectrum of systemic symptoms including fever, chills, arthralgia, myalgia, facial flushing, facial edema, vomiting, weakness, shortness of breath, hypotension, syncope, chest tightness, or angina can occur immediately following or up to 24 hours after administration of Kyprolis. Administration of dexamethasone prior to Kyprolis reduces the incidence and severity of reactions. Tumor lysis syndrome (TLS) occurred following Kyprolis administration in < 1 percent of patients. Patients with multiple myeloma and a high tumor burden should be considered to be at greater risk for TLS.

Thrombocytopenia following Kyprolis administration resulted in a dose reduction in 1% of patients and discontinuation of treatment with Kyprolis in < 1% of patients.

Cases of hepatic failure, including fatal cases, have been reported (< 1%). Kyprolis can cause elevations of serum transaminases and bilirubin.

There are no adequate and well-controlled studies in pregnant women using Kyprolis. Females of reproductive potential should be advised to avoid becoming pregnant while being treated with Kyprolis.

The most common serious adverse reactions were pneumonia, acute renal failure, pyrexia, and congestive heart failure. The most common adverse reactions (incidence of 30% or greater) observed in clinical trials of patients with multiple myeloma were fatigue, anemia, nausea, thrombocytopenia, dyspnea, diarrhea, and pyrexia. Serious adverse reactions were reported in 45% of patients.

Full prescribing information is available at www.onyx.com.

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.

About Onyx Pharmaceuticals, Inc.
Based in South San Francisco, California, Onyx Pharmaceuticals, Inc., an Amgen subsidiary, is a biopharmaceutical company engaged in the development and commercialization of innovative therapies for improving the lives of people with cancer. The company is focused on developing novel medicines that target key molecular pathways. For more information about Onyx, visit the company's website at www.onyx.com. Onyx Pharmaceuticals is on Twitter. Sign up to follow our Twitter feed @OnyxPharm at www.twitter.com/OnyxPharm.

Forward-Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen or us) 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 Inc., including Amgen Inc.'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 Inc.'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 27, 2014, 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 and our partners 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 (including products of our wholly-owned subsidiaries) 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 Amgen and its partners routinely obtain patents for their products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' 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. Our efforts to integrate the operations of companies we have acquired may not be successful.

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. 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.

CONTACT:
Amgen, Thousand Oaks
Kristen Davis, 805-447-3008 (media)
Arvind Sood, 805-447-1060 (investors)
Onyx, South San Francisco
Danielle Bertrand, 650-266-2114 (media)

Logo - http://photos.prnewswire.com/prnh/20081015/AMGENLOGO
Logo - http://photos.prnewswire.com/prnh/20131107/LA12955LOGO

SOURCE Amgen