Amgen Highlights Key Clinical Data to be Presented at European Society for Medical Oncology Congress

October 5, 2010

THOUSAND OAKS, Calif., Oct 05, 2010 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN) today announced that results from several important studies from the Company's oncology portfolio will be presented at the 35th European Society for Medical Oncology (ESMO) Congress, Oct. 8-12, 2010, in Milan, Italy.

"Cancer is a complex disease which requires innovative therapeutic approaches. Amgen is exploring numerous biologic pathways to develop novel therapies to treat cancer and lessen the side effects of cancer and its treatment," said Willard Dere, M.D., senior vice president and international chief medical officer at Amgen. "The data being presented at this year's ESMO Congress, including new denosumab and AMG 386 analyses, reflect the breadth and diversity of Amgen's oncology portfolio."

Abstracts will be available on the ESMO website at http://www.esmo.org following the meeting.

SELECTED ABSTRACTS INCLUDE:

Denosumab

- **Comparison of denosumab versus zoledronic acid (ZA) for treatment of bone metastases in advanced cancer patients: an integrated analysis of 3 pivotal trials**

  (Abstract Number 1249P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

- **Effects of denosumab vs. zoledronic acid (ZA) on pain in patients (Pts) with advanced cancer and bone metastases: an integrated analysis of 3 pivotal trials**

  (Abstract Number 1248P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

- **Health resource utilization (HRU) associated with skeletal-related events (SREs) in patients (pts) with bone metastases (BM) - U.S. interim analysis (IA) results from a multinational observational study**

  (Abstract Number 1101P; Poster; Saturday, Oct. 9, 1:00-2:00 p.m. CET, Hall 3)

Pipeline

- **A randomized, double-blind, placebo-controlled Phase 2 study of AMG 386 plus weekly paclitaxel in patients (pts) with advanced ovarian cancer**

  (Abstract Number 975PD; Poster Discussion; Saturday, Oct. 9, 1:00 p.m. CET, Yellow Hall 1)

- **Exposure-response relationships of AMG 386 in combination with weekly paclitaxel in advanced ovarian cancer: facilitation of Phase 3 dose selection by population pharmacokinetic/pharmacodynamic (PK/PD) modeling**

(Abstract Number 983P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

- **Open-label phase 1b study of AMG 386, a selective angiopoietin1/2-neutralizing peptibody, in combination with sorafenib or sunitinib in advanced renal cell carcinoma (RCC): interim results**

  (Abstract Number 505P; Poster; Monday, Oct. 11, 12:30-1:30 p.m. CET, Hall 3)

- **Conatumumab (CON) or AMG 479 or placebo (pbo) + gemcitabine (gem) in patients (pts) with metastatic pancreatic cancer (mPC): a placebo-controlled, randomized, Phase 2 study**

  (Abstract Number 741P; Poster; Saturday, Oct. 9, 1:00-2:00 p.m. CET, Hall 3)

- **Safety and pharmacokinetics of first-line AMG 479 (MAb to IGF1R) or AMG 102 (MAb to HGF/SF) with platinum-based chemotherapy in extensive-stage small cell lung cancer (SCLC)**

  (Abstract Number 444P; Poster; Monday, Oct. 11, 12:30-1:30 p.m. CET, Hall 3)

Vectibix(R) (panitumumab)

- **Primary efficacy and safety results of SPECTRUM, a Phase 3 trial in patients (pts) with recurrent and/or metastatic squamous cell carcinoma of the head and neck (SCCHN) receiving chemotherapy with or without panitumumab (pmab)**

  (Abstract Number LBA26; Oral Presentation; Monday, Oct. 11, 1:30-2:45 p.m. CET, Blue Hall)

- **Single-centre experience of quality assurance (QA) measures in a Phase 2 trial of radiotherapy (RT) + panitumumab vs chemo-RT (CRT) in patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN)**

  (Abstract Number 1024P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

- **Survival after surgical resection of hepatic metastases from colorectal cancer: a systematic review and meta-analysis**

  (Abstract Number 632P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

- **Panitumumab (pmab) regimen in second-line monotherapy (PRISM) in patients (pts) with recurrent (R) or metastatic (M) squamous cell carcinoma of the head and neck (SCCHN): interim safety analysis**

  (Abstract Number 1036P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

- **Phase II study with panitumumab, oxaliplatin, 5-fluorouracil and concurrent radiotherapy in high-risk locally advanced rectal cancer patients (STARPAN/STAR-02 study)**

(Abstract Number 654P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

- **Circulating level of VEGF, E-selectin, TGF-a, EGF and 18F-FDG PET uptake in locally advanced rectal cancer (LARC) patients treated with chemoradiation (CTRT) and panitumumab (StarPan/STAR-02 Phase II Study)**

  (Abstract Number 661P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

- **Efficacy and safety of second-line treatment with panitumumab plus irinotecan, both given every three weeks (Q3W), in patients (pts) with wild-type (WT) K-RAS metastatic colorectal cancer (mCRC): a study from the Spanish Cooperative Group for the Treatment of Digestive Tumors (TTD)**

  (Abstract Number 583PD; Poster Discussion; Saturday, Oct. 9, 1:00 p.m. CET, Orange Hall 2+3)

- **Current chemotherapy and monoclonal antibody use patterns in metastatic colorectal cancer in Western Europe**

  (Abstract Number 611P; Poster Discussion; Sunday, Oct. 10, 12:30 p.m. CET, Hall 3)

- **Clinical and economic burden of toxicities associated with monoclonal antibodies for metastatic colorectal cancer (mCRC)**

  (Abstract Number 612P; Poster Discussion; Sunday, Oct. 10, 12:30 p.m. CET, Hall 3)

Neulasta(R) (pegfilgrastim)

- **Granulocyte colony stimulating factor (G-CSF) prophylaxis and febrile neutropenia (FN) incidence in patients with solid tumours receiving myelotoxic chemotherapy who are assessed as high risk for FN: IMPACT SOLID study**

  (Abstract Number 1238PD; Poster Discussion; Saturday, Oct. 9, 1:15 p.m. CET, Yellow 3)

- **Administration of granulocyte-colony stimulating factors (G-CSF) in solid tumors. An Italian observational study by the OBSERVE study group**

  (Abstract Number 1256P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

Aranesp(R) (darbepoetin alfa)

- **Darbepoetin alfa dosing weekly and every three weeks in cancer patients with chemotherapy-induced anaemia - efficacy data from the CHOICE study**

  (Abstract Number 1267P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

- **Anemia and darbepoetin alfa administration in patients treated with CHOP+/-R chemotherapy: results from an observational study of patients with non-Hodgkin lymphoma**

  (Abstract Number 1270P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

- **Darbepoetin alfa in the treatment of chemotherapy-induced anaemia; effects of target haemoglobin label change: data from the APRIORI study**

  (Abstract Number 1268P; Poster; Sunday, Oct. 10, 12:30-1:30 p.m. CET, Hall 3)

For the latest updates on Amgen's presence at the ESMO Congress and other Amgen news, follow us on Twitter: **@Amgen.**

About Denosumab and Amgen's Research in Bone Biology

Denosumab is the first fully human monoclonal antibody in late stage clinical development that specifically targets RANK Ligand, the essential regulator of osteoclasts (the cells that breakdown bone). The denosumab development program is the largest ever initiated by Amgen. Thisbroad and deep development program demonstrates Amgen's commitment to researching anddelivering pioneering medicines to patients with unmet medical needs. Amgen is studyingdenosumab in numerous tumor types across the spectrum of cancer-related bone diseases.

Over 11,000 patients have been enrolled in the denosumab oncology clinical trials, testing the drug for the reduction of SREs in patients with breast and prostate cancer, as well as other solid tumors and multiple myeloma, for the amelioration of treatment-induced bone loss in patients with non-metastatic breast or prostate cancers, and for its potential to delay bone metastases in prostate and breast cancer.

Overall rates of adverse events and serious adverse events, including infections, were generally similar between the two arms. Osteonecrosis of the jaw was infrequent (52 patients receiving denosumab as compared with 37 patients receiving Zometa) and there was no statistically significant difference between treatment arms. As with previous studies in advanced cancer patients, hypocalcemia was more frequent in the denosumab arm. Both overall survival and the time to cancer progression were balanced.

About Vectibix

Vectibix is the first fully human anti-EGFR antibody approved by the United States (U.S.) Food and Drug Administration (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 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.

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. Use of Vectibix is not recommended for the treatment of colorectal cancer with these mutations.

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. Vectibix has been launched in more than 20 European Union countries, Russia, Israel, Switzerland, Australia, Canada and Japan. Applications in the rest of the world are pending.

Important U.S. Product Safety Information

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 1 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.

Important European Product Safety Information

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

Vectibix is indicated as monotherapy for the treatment of patients with EGFR-expressing, metastatic colorectal carcinoma (mCRC) with nonmutated (wild-type) KRAS 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.

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.

Vectibix should not be administered in combination with oxaliplatin-containing chemotherapy to mCRC patients with mutant KRAS tumours or for whom KRAS tumour status is unknown.

About Neulasta and NEUPOGEN(R)

Neulasta (pegfilgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

NEUPOGEN (filgrastim) is indicated to decrease the incidence of infection' as manifested by febrile neutropenia' in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Please refer to the Important European Product Safety Information section for approved indications in the EU.

Important U.S. Product Safety Information

Do not administer Neulasta or NEUPOGEN to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim. NEUPOGEN is contraindicated in patients with known hypersensitivity to E. coli-derived proteins, such as filgrastim.

Serious allergic reactions, including anaphylaxis, can occur in patients receiving Neulasta or NEUPOGEN. Permanently discontinue Neulasta or NEUPOGEN in patients with serious allergic reactions.

Splenic rupture, including fatal cases, can occur following the administration of Neulasta and NEUPOGEN.

Acute respiratory distress syndrome (ARDS) can occur in patients receiving Neulasta or NEUPOGEN.

Alveolar hemorrhage, manifesting as pulmonary infiltrates and hemoptysis requiring hospitalization, has been reported in healthy donors undergoing peripheral blood progenitor cell mobilization, an unapproved use of NEUPOGEN. Hemoptysis resolved with discontinuation of NEUPOGEN.

Bone pain and pain in extremity occurred at a higher incidence in Neulasta-treated patients as compared with placebo-treated patients. In clinical trials involving NEUPOGEN, bone pain was most frequently reported adverse event.

Important European Product Safety Information

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

NEUPOGEN is indicated for reduction in duration of neutropenia and incidence of febrile neutropenia after established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes); reduction in duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of NEUPOGEN are similar in adults and children receiving cytotoxic chemotherapy. NEUPOGEN is indicated for mobilisation of peripheral blood progenitor cells (PBPCs); long-term treatment to increase neutrophil counts and reduce incidence and duration of infection-related events in patients with severe congenital, cyclic, or idiopathic neutropenia treatment of persistent neutropenia in patients with advanced HIV infection.

NEUPOGEN is contraindicated in patients with hypersensitivity to filgrastim or excipients. Not to be used for escalation of cytotoxic chemotherapy doses above established regimens or administered to patients with severe congenital neutropenia (Kostman's Syndrome) with abnormal cytogenetics.

Administer NEUPOGEN with caution in secondary AML. Safety and efficacy of NEUPOGEN not established in *de novo* AML patients < 55 years with good cytogenetics (t(8;21), t(15;17) and inv(16)). The onset of pulmonary signs (cough, fever, dyspnoea) in association with radiological signs of pulmonary infiltrates and deterioration in pulmonary function may be preliminary signs of Acute Respiratory Distress Syndrome (ARDS). Discontinue NEUPOGEN and give appropriate treatment.

Other adverse events of special importance associated with NEUPOGEN include GvHD and fatalities in patients receiving G-CSF after allogeneic bone marrow transplantation, very rare cases of splenic rupture reported in healthy donors and patients, and hypersensitivity-type reactions in cancer patients. NEUPOGEN should be permanently discontinued in patients who experience a serious allergic reaction. NEUPOGEN is not recommended in period 24 hours before to 24 hours after chemotherapy.

Neulasta is indicated for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

Neulasta is contraindicated in patients with hypersensitivity to pegfilgrastim or excipients.

Neulasta should not be used in patients with MDS, CML and secondary AML. The safety and efficacy of Neulasta administration in *de novo* AML patients aged < 55 years with cytogenetics t(15;17) have not been established.

Neulasta should be discontinued following preliminary signs of ARDS. Spleen size should be carefully monitored and caution exercised when administering in patients with sickle cell disease. Safety and efficacy of Neulasta for mobilisation of blood progenitor cells in patients or healthy donors has not been adequately evaluated.

Other adverse events of special importance associated with Neulasta include bone pain, allergic-type reactions including anaphylaxis (pegfilgrastim should be permanently discontinued in patients who experience a serious allergic reaction) and very rare cases of splenic rupture including fatal

cases. Neulasta should be administered approximately 24 hours after administration of cytotoxic chemotherapy.

About Aranesp

Aranesp was approved by the FDA in 2001 for the treatment of anemia associated with CRF for patients on dialysis and patients not on dialysis. The European Commission granted marketing authorization for the same indication in 2001 and subsequently updated it for CRF patients with symptomatic anemia in 2008.

In 2002, the FDA approved Aranesp for the treatment of anemia caused by concomitantly administered chemotherapy in patients with nonmyeloid malignancies. The European Commission authorized the treatment of anemia caused by concomitantly administered chemotherapy in patients with non-haematological malignancies in 2002 and extended it to include non-myeloid malignancies in patients receiving chemotherapy in 2003.

Important U.S. Product Safety Information

Aranesp is indicated for the treatment of anemia due to the effect of concomitantly administered chemotherapy based on studies that have shown a reduction in the need for red blood cell transfusions in patients with metastatic, non-myeloid malignancies. Studies to determine whether Aranesp increases mortality or decreases progression-free/recurrence-free survival are ongoing.

- Aranesp is not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy.
- Aranesp is not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure due to the absence of studies that adequately characterize the impact of Aranesp on progression-free and overall survival.
- Aranesp use has not been demonstrated in controlled clinical trials to improve symptoms of anemia, quality of life, fatigue, or patient well-being.

WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR EVENTS, THROMBOEMBOLIC EVENTS, STROKE AND INCREASED RISK OF TUMOR PROGRESSION OR RECURRENCE

Cancer:

- ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in some clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.
- To decrease these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusion.
- Because of these risks, prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense Aranesp, EPOGEN(R) or PROCRIT(R) to patients with cancer. To enroll in the ESA APPRISE Oncology Program, visit http://www.esa-apprise.com/ or call 1-866-284-8089 for further assistance.
- Use ESAs only for treatment of anemia due to concomitant myelosuppressive chemotherapy.
- ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure.
- Discontinue following the completion of a chemotherapy course.
- ESAs are contraindicated in patients with uncontrolled hypertension.

Important European Product Safety Information

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

Aranesp is indicated for treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.

Aranesp is contraindicated in patients with poorly controlled hypertension.

Controlled clinical trials have not shown significant benefits attributable to the administration of epoetins when haemoglobin concentration is increased beyond the level necessary to control symptoms of anaemia and to avoid blood transfusion.

In controlled clinical studies, use of Aranesp and other ESAs have shown:

- shortened time to tumour progression in patients with advanced head and neck cancer receiving radiation therapy when administered to target Hb > 14 g/dL; ESAs are not indicated for use in this patient population
- shortened overall survival and increased deaths attributed to disease progression at 4 months in patients with metastatic breast cancer receiving chemotherapy when administered to target Hb 12-14 g/dL
- increased risk of death when administered to target Hb of 12 g/dl (7.5 mmol/l) in patients with active malignant disease receiving neither chemotherapy nor radiation therapy; ESAs are not indicated for use in this patient population.

In some clinical situations blood transfusion should be the preferred treatment for the management of anaemia in patients with cancer. The decision to administer recombinant erythropoietins should be based on a benefit-risk assessment with the participation of the individual patient, which should take into account the specific clinical context. Factors that should be considered in this assessment should include the type of tumour and its stage; the degree of anaemia; life-expectancy; the environment in which the patient is being treated; and patient preference.

In patients with solid tumours or lymphoproliferative malignancies, if Hb >12 g/dL, the dose should be reduced/held to minimise the potential risk of thromboembolic events.

Discontinue use after the end of chemotherapy.

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 http://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 Oct. 5, 2010 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 thirdparty 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 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 U.S. 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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