



Amgen To Present New KYPROLIS® (Carfilzomib) And XGEVA® (Denosumab) Data At The 16th International Myeloma Workshop

March 1, 2017

Detailed Results From Phase 3 Head-to-Head ENDEAVOR Trial Show KYPROLIS Significantly Improved Overall Survival Compared to Velcade® (Bortezomib) in Relapsed or Refractory Multiple Myeloma Patients **Late-Breaking Results From Largest International Trial Conducted in Multiple Myeloma Show XGEVA was Non-Inferior Versus Zoledronic Acid in Delaying Bone Complications**

THOUSAND OAKS, Calif., March 1, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that new data from the KYPROLIS® (carfilzomib) and XGEVA® (denosumab) clinical development programs will be presented at the 16th International Myeloma Workshop (IMW), March 1-4, 2017, in New Delhi. Highlighted presentations include detailed results from the planned overall survival (OS) interim analysis of the Phase 3 head-to-head ENDEAVOR trial which showed that patients treated with KYPROLIS and dexamethasone lived longer than those treated with Velcade® (bortezomib) and dexamethasone, as well as detailed results from the Phase 3 study in which XGEVA demonstrated non-inferiority to zoledronic acid in delaying bone complications in patients with multiple myeloma.

"Amgen is committed to advancing innovative treatments for patients with multiple myeloma across the disease continuum, including treatments to help patients live longer and supportive therapies that may help to address its impact," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We look forward to sharing new data on KYPROLIS, demonstrating for the first time an overall survival benefit in relapsed or refractory multiple myeloma over a current standard of care regimen, along with XGEVA data, showing its potential as a novel agent in preventing bone complications in multiple myeloma patients."

Detailed results will be presented from the Phase 3 ENDEAVOR study which showed that KYPROLIS improved OS in patients with relapsed or refractory multiple myeloma.

- **Overall Survival of Patients with Relapsed or Refractory Multiple Myeloma Treated with Carfilzomib and Dexamethasone versus Bortezomib and Dexamethasone: Interim Analysis from the Randomized Phase 3 ENDEAVOR Trial**

Late-Breaking Oral Presentation, Saturday, March 4, 7:30 a.m. – 8:30 a.m. IST, at Hotel Pullman New Delhi Aerocity, Peacock Ballroom.

Adverse events observed in this updated analysis were consistent with those previously reported for ENDEAVOR. The most common adverse events (greater than or equal to 20 percent) in the KYPROLIS arm were anemia, diarrhea, pyrexia, dyspnea, fatigue, hypertension, cough, insomnia, upper respiratory tract infection, peripheral edema, nausea, bronchitis, asthenia, back pain, thrombocytopenia and headache.

Detailed results will be presented from the Phase 3 '482 trial that demonstrated XGEVA was non-inferior to zoledronic acid in delaying the time to first on-study skeletal-related event (SRE) in patients with multiple myeloma. These data are being shared with regulatory authorities worldwide to seek approval for this investigational use. XGEVA is a fully human monoclonal antibody that binds to and neutralizes RANK ligand (RANKL) – an essential mediator of osteoclast formation, activation and survival – thereby inhibiting osteoclast-mediated bone destruction.

- **An International, Randomized, Double Blind Trial Comparing Denosumab With Zoledronic Acid (ZA) for the Treatment of Bone Disease in Patients (Pts) With Newly Diagnosed Multiple Myeloma**

Abstract #546, Late-Breaking Oral Presentation, Saturday, March 4, 8:15 a.m. – 8:30 a.m. IST, at Hotel Pullman New Delhi Aerocity, Peacock Ballroom.

Additional KYPROLIS abstracts at IMW include new sub-analyses from the ASPIRE, ENDEAVOR and CHAMPION clinical trial programs, as well as results from the CLARION study. These results provide further insights into the safety and efficacy of KYPROLIS in different combinations and patient groups.

- **Updated Results from ASPIRE and ENDEAVOR, Randomized, Open-Label, Multicenter Phase 3 Studies of Carfilzomib in Patients (Pts) with Relapsed/Refractory Multiple Myeloma (RRMM)**
Abstract #335, Poster Discussion, Friday, March 3, 6 p.m. – 7 p.m. IST, at JW Marriott Hotel New Delhi Aerocity, Crystal Ballroom 1-2.
- **Efficacy and Safety of Once-Weekly Carfilzomib and Dexamethasone in Patients With Relapsed or Refractory Multiple Myeloma: Secondary Analysis from the CHAMPION-1 Study by Prior Lines of Therapy**
Abstract #285, Poster Session, Thursday, March 2, 7 a.m. – 6 p.m. IST, at JW Marriott Hotel New Delhi Aerocity, Crystal Ballroom 1-2.
- **A Multicenter, Open-Label, Phase 1b Study of Carfilzomib, Cyclophosphamide, and Dexamethasone in Newly Diagnosed Multiple Myeloma Patients (CHAMPION-2)**
Abstract #210, Oral Presentation, Thursday, March 2, 3:04 p.m. – 3:15 p.m. IST, at Hotel Pullman New Delhi Aerocity, Peacock Ballroom.
- **Phase 3 Study (CLARION) of Carfilzomib, Melphalan, Prednisone (KMP) versus Bortezomib, Melphalan, Prednisone (VMP) in Newly Diagnosed Multiple Myeloma (NDMM)**

Abstract #373, Late-Breaking Oral Presentation, Saturday, March 4, 7:45 a.m. – 8 a.m. IST, at Hotel Pullman New Delhi Aerocity, Peacock Ballroom.

KYPROLIS is the only proteasome inhibitor to show superior OS in a head-to-head trial with a standard of care regimen, and superior progression-free survival in two Phase 3 studies in relapsed multiple myeloma patients. KYPROLIS is available for patients whose myeloma has relapsed or become resistant to another treatment.

Abstracts are currently available on the IMW [website](#).

About Multiple Myeloma and Bone Complications

Multiple myeloma is the second most common hematologic cancer, and it develops in plasma cells located in the bone microenvironment.^{1,2} It is characterized by a recurring pattern of remission and relapse, with patients eventually becoming refractory to treatment.³ Each year an estimated 114,000 new cases of multiple myeloma are diagnosed worldwide, resulting in more than 80,000 deaths per year.¹

Osteolytic bone lesions accompany multiple myeloma and are part of diagnosis (CRAB criteria). These lesions can increase the risk of bone complications over the course of the disease.^{4,5} Bone complications, also known as SREs, are defined as radiation to bone, pathologic fracture, surgery to bone, and spinal cord compression.

About Amgen's Commitment to Oncology

Amgen Oncology is committed to helping patients take on some of the toughest cancers, such as those that have been resistant to drugs, those that progress rapidly through the body and those where limited treatment options exist. Amgen's supportive care treatments help patients combat certain side effects of strong chemotherapy, and our targeted medicines and immunotherapies focus on more than a dozen different malignancies, ranging from blood cancers to solid tumors. With decades of experience providing therapies for cancer patients, Amgen continues to grow its portfolio of innovative and biosimilar oncology medicines.

About XGEVA® (denosumab)

XGEVA targets the RANKL pathway to prevent the formation, function and survival of osteoclasts, which break down bone. XGEVA is indicated for the prevention of SREs in patients with bone metastases from solid tumors and for treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. XGEVA is also indicated in the United States (U.S.) for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. XGEVA is not indicated for the prevention of SREs in patients with multiple myeloma.

U.S. Important Safety Information

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, especially in the first weeks of initiating therapy, 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.

An increased risk of hypocalcemia has been observed in clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction (creatinine clearance less than 30 mL/minute and/or on dialysis), and with inadequate/no calcium supplementation. Monitor calcium levels and calcium and vitamin D intake.

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) has occurred in patients receiving XGEVA, manifesting as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration, or gingival erosion. Persistent pain or slow healing of the mouth or jaw after dental surgery may also be manifestations of ONJ. In clinical trials in patients with osseous metastasis, the incidence of ONJ was higher with longer duration of exposure.

Patients with a history of tooth extraction, poor oral hygiene, or use of a dental appliance are at a greater risk to develop ONJ. Other risk factors for the development of ONJ include immunosuppressive therapy, treatment with angiogenesis inhibitors, systemic corticosteroid, diabetes, and gingival infections.

Perform an oral examination and appropriate preventive dentistry prior to the initiation of XGEVA and periodically during XGEVA therapy. Advise patients regarding oral hygiene practices. Avoid invasive dental procedures during treatment with XGEVA. Consider temporarily interrupting XGEVA therapy if an invasive dental procedure must be performed.

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.

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. They may be bilateral and many patients report prodromal pain in the affected area, usually presenting as dull, aching thigh pain, weeks to months before a complete fracture occurs. A number of

reports note that patients were also receiving treatment with glucocorticoids (e.g. prednisone) at the time of fracture. 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. Based on findings in animals, XGEVA is expected to result in adverse reproductive effects. Advise females of reproductive potential to use highly effective contraception during therapy, and for at least five months after the last dose of XGEVA. Apprise the patient of the potential hazard to a fetus if XGEVA is used during pregnancy or if the patient becomes pregnant while patients are exposed to 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.

The most common adverse reactions in patients receiving XGEVA for giant cell tumor of bone were arthralgia, headache, nausea, back pain, fatigue, and pain in extremity. The most common serious adverse reactions were osteonecrosis of the jaw and osteomyelitis. The most common adverse reactions resulting in discontinuation of XGEVA were osteonecrosis of the jaw and tooth abscess or tooth infection.

The most common adverse reactions in patients receiving XGEVA for hypercalcemia of malignancy were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.

Denosumab is also marketed as Prolia[®] in other indications.

Please visit www.amgen.com or www.xgeva.com for Full U.S. Prescribing Information.

About KYPROLIS[®] (carfilzomib)

Proteasomes play an important role in cell function and growth by breaking down proteins that are damaged or no longer needed. KYPROLIS has been shown to block proteasomes, leading to an excessive build-up of proteins within cells. In some cells, KYPROLIS can cause cell death, especially in myeloma cells because they are more likely to contain a higher amount of abnormal proteins.

KYPROLIS is approved in the U.S. for the following:

- In combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.
- As a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

KYPROLIS is also approved in Argentina, Australia, Bahrain, Canada, Hong Kong, Israel, Japan, Kuwait, Lebanon, Macao, Mexico, Thailand, Colombia, S. Korea, Canada, Qatar, Switzerland, United Arab Emirates, Turkey, Russia, Brazil, India and the European Union. Additional regulatory applications for KYPROLIS are underway and have been submitted to health authorities worldwide.

For more U.S. information, please visit www.kyprolis.com.

IMPORTANT SAFETY INFORMATION

Cardiac Toxicities

- New onset or worsening of pre-existing cardiac failure (e.g., congestive heart failure, pulmonary edema, decreased ejection fraction), restrictive cardiomyopathy, myocardial ischemia, and myocardial infarction including fatalities have occurred following administration of KYPROLIS. Some events occurred in patients with normal baseline ventricular function. Death due to cardiac arrest has occurred within one day of KYPROLIS administration.
- Monitor patients for clinical signs or symptoms of cardiac failure or cardiac ischemia. Evaluate promptly if cardiac toxicity is suspected. Withhold KYPROLIS for Grade 3 or 4 cardiac adverse events until recovery, and consider whether to restart KYPROLIS at 1 dose level reduction based on a benefit/risk assessment.
- While adequate hydration is required prior to each dose in Cycle 1, monitor all patients for evidence of volume overload, especially patients at risk for cardiac failure. Adjust total fluid intake as clinically appropriate in patients with baseline cardiac failure or who are at risk for cardiac failure.
- Patients \geq 75 years, the risk of cardiac failure is increased. Patients with New York Heart Association Class III and IV heart failure, recent myocardial infarction, conduction abnormalities, angina, or arrhythmias may be at greater risk for cardiac complications and should have a comprehensive medical assessment (including blood pressure and fluid management) prior to starting treatment with KYPROLIS and remain under close follow-up.

Acute Renal Failure

- Cases of acute renal failure and renal insufficiency adverse events (including renal failure) have occurred in patients receiving KYPROLIS. Acute renal failure was reported more frequently in patients with advanced relapsed and refractory multiple myeloma who received KYPROLIS monotherapy. Monitor renal function with regular measurement of the serum creatinine and/or estimated creatinine clearance. Reduce or withhold dose as appropriate.

Tumor Lysis Syndrome

- Cases of Tumor Lysis Syndrome (TLS), including fatal outcomes, have occurred in patients receiving KYPROLIS. Patients with multiple myeloma and a high tumor burden should be considered at greater risk for TLS. Adequate hydration is required prior to each dose in Cycle 1, and in subsequent cycles as needed. Consider uric acid lowering drugs in patients at risk for TLS. Monitor for evidence of TLS during treatment and manage promptly. Withhold KYPROLIS until TLS is resolved.

Pulmonary Toxicity

- Acute Respiratory Distress Syndrome (ARDS), acute respiratory failure, and acute diffuse infiltrative pulmonary disease such as pneumonitis and interstitial lung disease have occurred in patients receiving KYPROLIS. Some events have been fatal. In the event of drug-induced pulmonary toxicity, discontinue KYPROLIS.

Pulmonary Hypertension

- Pulmonary arterial hypertension (PAH) was reported in patients treated with KYPROLIS. Evaluate with cardiac imaging and/or other tests as indicated. Withhold KYPROLIS for PAH until resolved or returned to baseline and consider whether to restart KYPROLIS based on a benefit/risk assessment.

Dyspnea

- Dyspnea was reported in patients treated with KYPROLIS. Evaluate dyspnea to exclude cardiopulmonary conditions including cardiac failure and pulmonary syndromes. Stop KYPROLIS for Grade 3 or 4 dyspnea until resolved or returned to baseline. Consider whether to restart KYPROLIS based on a benefit/risk assessment.

Hypertension

- Hypertension, including hypertensive crisis and hypertensive emergency, has been observed with KYPROLIS. Some of these events have been fatal. Monitor blood pressure regularly in all patients. If hypertension cannot be adequately controlled, withhold KYPROLIS and evaluate. Consider whether to restart KYPROLIS based on a benefit/risk assessment.

Venous Thrombosis

- Venous thromboembolic events (including deep venous thrombosis and pulmonary embolism) have been observed with KYPROLIS. Thromboprophylaxis is recommended for patients being treated with the combination of KYPROLIS with dexamethasone or with lenalidomide plus dexamethasone. The thromboprophylaxis regimen should be based on an assessment of the patient's underlying risks.
- Patients using oral contraceptives or a hormonal method of contraception associated with a risk of thrombosis should consider an alternative method of effective contraception during treatment with KYPROLIS in combination with dexamethasone or lenalidomide plus dexamethasone.

Infusion Reactions

- Infusion reactions, including life-threatening reactions, have occurred in patients receiving KYPROLIS.
- Symptoms include fever, chills, arthralgia, myalgia, facial flushing, facial edema, vomiting, weakness, shortness of breath, hypotension, syncope, chest tightness, or angina. These reactions can occur immediately following or up to 24 hours after administration of KYPROLIS. Premedicate with dexamethasone to reduce the incidence and severity of infusion reactions. Inform patients of the risk and of symptoms of an infusion reaction and to contact a physician immediately if they occur.

Hemorrhage

- Fatal or serious cases of hemorrhage have been reported in patients receiving KYPROLIS. Hemorrhagic events have included gastrointestinal, pulmonary, and intracranial hemorrhage and epistaxis. Promptly evaluate signs and symptoms of blood loss. Reduce or withhold dose as appropriate.

Thrombocytopenia

- KYPROLIS causes thrombocytopenia with recovery to baseline platelet count usually by the start of the next cycle. Thrombocytopenia was reported in patients receiving KYPROLIS. Monitor platelet counts frequently during treatment with KYPROLIS. Reduce or withhold dose as appropriate.

Hepatic Toxicity and Hepatic Failure

- Cases of hepatic failure, including fatal cases, have been reported during treatment with KYPROLIS. KYPROLIS can cause increased serum transaminases. Monitor liver enzymes regularly regardless of baseline values. Reduce or withhold

dose as appropriate.

Thrombotic Microangiopathy

- Cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), including fatal outcome have occurred in patients receiving KYPROLIS. Monitor for signs and symptoms of TTP/HUS. Discontinue KYPROLIS if diagnosis is suspected. If the diagnosis of TTP/HUS is excluded, KYPROLIS may be restarted. The safety of reinitiating KYPROLIS therapy in patients previously experiencing TTP/HUS is not known.

Posterior Reversible Encephalopathy Syndrome (PRES)

- Cases of PRES have occurred in patients receiving KYPROLIS. PRES was formerly known as Reversible Posterior Leukoencephalopathy Syndrome. Consider a neuro-radiological imaging (MRI) for onset of visual or neurological symptoms. Discontinue KYPROLIS if PRES is suspected and evaluate. The safety of reinitiating KYPROLIS therapy in patients previously experiencing PRES is not known.

Embryo-fetal Toxicity

- KYPROLIS can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals.
- Females of reproductive potential should be advised to avoid becoming pregnant while being treated with KYPROLIS. Males of reproductive potential should be advised to avoid fathering a child while being treated with KYPROLIS. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the patient should be apprised of the potential hazard to the fetus.

ADVERSE REACTIONS

- The most common adverse reactions occurring in at least 20% of patients treated with KYPROLIS in the combination therapy trials: anemia, neutropenia, diarrhea, dyspnea, fatigue, thrombocytopenia, pyrexia, insomnia, muscle spasm, cough, upper respiratory tract infection, hypokalemia.
- The most common adverse reactions occurring in at least 20% of patients treated with KYPROLIS in monotherapy trials: anemia, fatigue, thrombocytopenia, nausea, pyrexia, dyspnea, diarrhea, headache, cough, edema peripheral.

Please see full prescribing information at www.kyprolis.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 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 one of the world's leading independent biotechnology companies, 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 the current expectations and beliefs of Amgen. 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 reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. 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 results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including

biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and 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. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. 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. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. 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. Further, 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, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock.

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 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.

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