BLINCYTO® (BLINATUMOMAB) ADDED TO CHEMOTHERAPY SIGNIFICANTLY IMPROVES SURVIVAL IN NEWLY DIAGNOSED PEDIATRIC PATIENTS WITH B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (B-ALL)

December 7, 2024

Phase 3 Study Results Demonstrated Three Year, Disease-Free Survival of 96%

THOUSAND OAKS, Calif., Dec. 7, 2024 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced new data demonstrating that adding BLINCYTO® (blinatumomab) to chemotherapy significantly improves disease-free survival (DFS) in newly diagnosed pediatric patients with National Cancer Institute (NCI) standard risk (SR) B-cell acute lymphoblastic leukemia (B-ALL) of average or higher risk of relapse. The data are from a Phase 3 study (AALL1731) conducted by the Children's Oncology Group. The results were simultaneously published in the *New England Journal of Medicine* and will be presented during the plenary session on Sunday, Dec. 8, at 2 p.m. PT at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition in San Diego.

"Over the last decade, BLINCYTO has reshaped the treatment landscape for B-ALL, offering a critical lifeline for thousands of adult and pediatric patients," said Jay Bradner, M.D., executive vice president of Research and Development and chief scientific officer at Amgen. "These powerful new data leave us little doubt about the profound impact of this medicine for a large number of children affected by this disease. We are grateful to the Children's Oncology Group, along with the patients, families and clinical teams, for their dedication and partnership in advancing this critical study to improve the lives of children with cancer."

Based on the results of the first pre-specified interim analysis for efficacy, the study met its primary endpoint of DFS and study randomization was terminated early based on the recommendation from the data and safety monitoring committee due to the benefit observed in the BLINCYTO arm compared to the chemotherapy-only arm. Overall, the 3-year DFS was 96.0% for patients treated with chemotherapy plus BLINCYTO compared to 87.9% for those treated with only chemotherapy. The hazard ratio (HR) was 0.39 [95% confidence interval (CI) 0.24-0.64], indicating a 61% reduction in the risk of disease relapse, secondary malignant neoplasm or remission death with BLINCYTO. At 3 years, more patients remained alive and cancer free when treated with BLINCYTO plus chemotherapy compared to chemotherapy alone.

"The AALL1731 study results are truly practice-changing, further solidifying blinatumomab's role as the standard of care for a large number of children with B-ALL," said Sumit Gupta, M.D., Ph.D., FRCPC, co-chair of the Children's Oncology Group AALL1731 study and oncologist and clinician investigator, Division of Haematology/Oncology at The Hospital for Sick Children (SickKids) and associate professor of pediatrics at the University of Toronto. "These breakthrough data showing a significant improvement in disease-free survival are poised to bring substantial clinical value to children with newly diagnosed B-ALL."

The addition of BLINCYTO to chemotherapy in standard risk patients resulted in outcomes similar to those previously achieved in only the most favorable pediatric risk subsets. Among SR-Average patients, 3-year DFS was 97.5% for patients treated with BLINCYTO compared to 90.2% for those treated with only chemotherapy (HR 0.33, CI 0.15-0.69). For SR-High patients, 3-year DFS was 94.1% for those treated with BLINCYTO compared to 84.8% for those treated with only chemotherapy (HR 0.45, 95% CI 0.24-0.85).

"Relapsed ALL remains a major cause of pediatric cancer mortality, with nearly half of the relapses occurring in children with standard-risk B-ALL," said Rachel E. Rau, M.D., co-chair of the Children's Oncology Group AALL1731 study, pediatric hematologist-oncologist at Seattle Children's Hospital and associate professor of pediatrics at the University of Washington. "These findings underscore the progress made with blinatumomab in preventing relapse and support its role as a critical addition to current therapeutic strategies."

Safety results are consistent with the known safety profile of BLINCYTO. BLINCYTO has demonstrated a positive balance of benefits and risks, with only 0.3% of first courses associated with Grade 3+ cytokine release syndrome (CRS) and 0.7% with seizures. A higher risk of infections was observed in the BLINCYTO arm.

These results provide the first evidence supporting BLINCYTO for use in the consolidation phase in newly diagnosed pediatric Philadelphia chromosome-negative (Ph-) B-ALL patients. This groundbreaking first-in-class Bispecific T-cell Engager (BiTE®) therapy is now backed by additional evidence reinforcing its role in redefining a standard of care for both adult and pediatric patients, starting from one month old, regardless of measurable residual disease (MRD) status. The findings further establish BLINCYTO as a versatile first-line consolidation therapy across all ages and treatment backbones.

The NCI's Cancer Therapy Evaluation Program (CTEP), which sponsored the study will share data with the U.S. Food and Drug Administration as part of their ongoing communications relating to the trial.

About The Children's Oncology Group
The Children's Oncology Group (childrensoncologygroup.org), a member of the NCI National Clinical Trials Network (NCTN), is the world's largest organization devoted exclusively to childhood and adolescent cancer research. The Children's Oncology Group unites over 10,000 experts in childhood cancer at more than 200 leading children's hospitals, universities and cancer centers across North America, Australia, New Zealand and Saudi Arabia in the fight against childhood cancer. Today, more than 80% of the 15,000 children and adolescents diagnosed with cancer each year in the United States are cared for at Children's Oncology Group member institutions. Research performed by Children's Oncology Group institutions over the past 50 years has transformed childhood cancer from a virtually incurable disease to one with a combined 5-year survival rate of 86%. The Children's Oncology Group's mission is to improve the cure rate and outcomes for all children with cancer.

About AALL1731 (NCT03914625)
The AALL1731 study was a Phase 3 randomized trial to determine if two non-sequential cycles of BLINCYTO added to chemotherapy improved disease-free survival (DFS) in children with newly diagnosed pediatric National Cancer Institute (NCI) standard risk (SR) B-cell acute lymphoblastic

leukemia (B-ALL). The study enrolled 4,264 newly diagnosed NCI SR B-ALL patients, of whom 2,334 were risk stratified at the end of induction therapy as either SR-Average or SR-High. At the first planned interim efficacy analysis (data cutoff June 30, 2024), 1,440 of the eligible and evaluable patients had been randomized.

The AALL1731 study was designed and conducted independently from industry. The Cancer Therapy Evaluation Program (CTEP) of the NCI sponsored the trial and provided funding to the Children's Oncology Group to conduct the study. NCI is part of the National Institutes of Health (NIH). In addition, Amgen provided BLINCYTO and support through an NCI Cooperative Research and Development Agreement.

About Acute Lymphoblastic Leukemia (ALL)
ALL, also known as acute lymphoblastic leukemia, is a fast-growing type of blood cancer that develops in the bone marrow and can sometimes spread to other parts of the body, including the lymph nodes, liver, spleen and central nervous system. ALL is a rare disease, with an estimated 6,550 new cases, affecting both children and adults, diagnosed in the U.S. in 2024.[1] B-ALL begins in immature cells that would normally develop into B-cell lymphocytes, which are white blood cells that grow in bone marrow.[2,3] B-ALL is the most common type of ALL, constituting approximately 75% of cases in adults and approximately 88% in children, the most common cancer in children.[4,5]

About BLINCYTO® (blinatumomab)
BLINCYTO is the first globally approved Bispecific T-cell Engager (BiTE®) immuno-oncology therapy that targets CD19 surface antigens on B cells. BiTE® molecules fight cancer by helping the body's immune system detect and target malignant cells by engaging T cells (a type of white blood cell capable of killing other cells perceived as threats) to cancer cells. By bringing T cells near cancer cells, the T cells can inject toxins and trigger cancer cell death (apoptosis). BiTE® immuno-oncology therapies are currently being investigated for their potential to treat a wide variety of cancers.

BLINCYTO was granted Breakthrough Therapy and Priority Review designations by the U.S. FDA and is approved in the U.S. for the treatment of:

- Adult and pediatric patients one month or older with CD19-positive Philadelphia chromosome-negative B-ALL during the consolidation phase of multiphase therapy.
- CD19-positive B-ALL in first or second complete remission with MRD greater than or equal to 0.1% in adults and pediatric patients one month or older.
- Relapsed or refractory CD19-positive B-ALL in adults and pediatric patients one month or older.

In the European Union (EU), BLINCYTO is indicated as monotherapy for the treatment of:

- Adults with Philadelphia chromosome-negative CD19-positive relapsed or refractory B-ALL. Patients with Philadelphia chromosome-positive B-ALL should have failed treatment with at least two tyrosine kinase inhibitors (TKIs) and have no alternative treatment options.
- Adults with Philadelphia chromosome-negative CD19-positive B-ALL in first or second complete remission with MRD greater than or equal to 0.1%.
- Pediatric patients aged 1 year or older with Philadelphia chromosome-negative CD19-positive B-ALL which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation.
- Pediatric patients aged 1 year or older with high-risk first relapsed Philadelphia chromosome-negative CD19-positive B-ALL as part of the consolidation therapy.

BLINCYTO® IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITIES including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- **Cytokine Release Syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® and treat with corticosteroids as recommended.**
- **Neurological toxicities, including immune effector cell-associated neurotoxicity syndrome (ICANS) which may be severe, life-threatening, or fatal, occurred in patients receiving BLINCYTO®. Interrupt or discontinue BLINCYTO® as recommended.**

Contraindications

BLINCYTO® is contraindicated in patients with a known hypersensitivity to blinatumomab or to any component of the product formulation.

Warnings and Precautions

- **Cytokine Release Syndrome (CRS):** CRS, which may be life-threatening or fatal, occurred in patients receiving BLINCYTO®. The median time to onset of CRS is 2 days after the start of infusion and the median time to resolution of CRS was 5 days among cases that resolved. Closely monitor and advise patients to contact their healthcare professional for signs and symptoms of serious adverse events such as fever, headache, nausea, asthenia, hypotension, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), increased total bilirubin (TBILI), and disseminated intravascular coagulation (DIC). The manifestations of CRS after treatment with BLINCYTO® overlap with those of infusion reactions, capillary leak syndrome (CLS), and hemophagocytic histiocytosis/macrophage activation

syndrome (MAS). Using all of these terms to define CRS in clinical trials of BLINCYTO®, CRS was reported in 15% of patients with R/R ALL, in 7% of patients with MRD-positive ALL, and in 16% of patients receiving BLINCYTO® cycles in the consolidation phase of therapy. If severe CRS occurs, interrupt BLINCYTO® until CRS resolves. Discontinue BLINCYTO® permanently if life-threatening CRS occurs. Administer corticosteroids for severe or life-threatening CRS.

- **Neurological Toxicities, including Immune Effector Cell-Associated Neurotoxicity Syndrome:** BLINCYTO® can cause serious or life-threatening neurologic toxicity, including ICANS. The incidence of neurologic toxicities in clinical trials was approximately 65%. The median time to the first event was within the first 2 weeks of BLINCYTO® treatment. The most common (≥ 10%) manifestations of neurological toxicity were headache and tremor. Grade 3 or higher neurological toxicities occurred in approximately 13% of patients, including encephalopathy, convulsions, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders. Manifestations of neurological toxicity included cranial nerve disorders. The majority of neurologic toxicities resolved following interruption of BLINCYTO®, but some resulted in treatment discontinuation.

  The incidence of signs and symptoms consistent with ICANS in clinical trials was 7.5%. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. There is limited experience with BLINCYTO® in patients with active ALL in the central nervous system (CNS) or a history of neurologic events. Patients with a history or presence of clinically relevant CNS pathology were excluded from clinical studies. Patients with Down Syndrome over the age of 10 years may have a higher risk of seizures with BLINCYTO® therapy.

  Monitor patients for signs and symptoms of neurological toxicities, including ICANS, and interrupt or discontinue BLINCYTO® as outlined in the PI. Advise outpatients to contact their healthcare professional if they develop signs or symptoms of neurological toxicities.

- **Infections:** Approximately 25% of patients receiving BLINCYTO® in clinical trials experienced serious infections such as sepsis, pneumonia, bacteremia, opportunistic infections, and catheter-site infections, some of which were life-threatening or fatal. Administer prophylactic antibiotics and employ surveillance testing as appropriate during treatment. Monitor patients for signs or symptoms of infection and treat appropriately, including interruption or discontinuation of BLINCYTO® as needed.

- **Tumor Lysis Syndrome (TLS),** which may be life-threatening or fatal, has been observed. Preventive measures, including pretreatment nontoxic cytoreduction and on-treatment hydration, should be used during BLINCYTO® treatment. Monitor patients for signs and symptoms of TLS and interrupt or discontinue BLINCYTO® as needed to manage these events.

- **Neutropenia and Febrile Neutropenia,** including life-threatening cases, have been observed. Monitor appropriate laboratory parameters (including, but not limited to, white blood cell count and absolute neutrophil count) during BLINCYTO® infusion and interrupt BLINCYTO® if prolonged neutropenia occurs.

- **Effects on Ability to Drive and Use Machines:** Due to the possibility of neurological events, including seizures and ICANS, patients receiving BLINCYTO® are at risk for loss of consciousness, and should be advised against driving and engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery while BLINCYTO® is being administered.

- **Elevated Liver Enzymes:** Transient elevations in liver enzymes have been associated with BLINCYTO® treatment with a median time to onset of 3 days. In patients receiving BLINCYTO®, although the majority of these events were observed in the setting of CRS, some cases of elevated liver enzymes were observed outside the setting of CRS, with a median time to onset of 19 days. Grade 3 or greater elevations in liver enzymes occurred in approximately 7% of patients outside the setting of CRS and resulted in treatment discontinuation in less than 1% of patients. Monitor ALT, AST, gamma-glutamyl transferase, and total blood bilirubin prior to the start of and during BLINCYTO® treatment. BLINCYTO® treatment should be interrupted if transaminases rise to > 5 times the upper limit of normal (ULN) or if total bilirubin rises to > 3 times ULN.

- **Pancreatitis:** Fatal pancreatitis has been reported in patients receiving BLINCYTO® in combination with dexamethasone in clinical trials and the post-marketing setting. Evaluate patients who develop signs and symptoms of pancreatitis and interrupt or discontinue BLINCYTO® and dexamethasone as needed.

- **Leukoencephalopathy:** Although the clinical significance is unknown, cranial magnetic resonance imaging (MRI) changes showing leukoencephalopathy have been observed in patients receiving BLINCYTO®, especially in patients previously

treated with cranial irradiation and antileukemic chemotherapy.

- **Preparation and administration** errors have occurred with BLINCYTO® treatment. Follow instructions for preparation (including admixing) and administration in the PI strictly to minimize medication errors (including underdose and overdose).

- **Immunization:** Vaccination with live virus vaccines is not recommended for at least 2 weeks prior to the start of BLINCYTO® treatment, during treatment, and until immune recovery following last cycle of BLINCYTO®.

- **Benzyl Alcohol Toxicity in Neonates:** Serious adverse reactions, including fatal reactions and the "gasping syndrome," have been reported in very low birth weight (VLBW) neonates born weighing less than 1500 g, and early preterm neonates (infants born less than 34 weeks gestational age) who received intravenous drugs containing benzyl alcohol as a preservative. Early preterm VLBW neonates may be more likely to develop these reactions, because they may be less able to metabolize benzyl alcohol.

  Use the preservative-free preparations of BLINCYTO® where possible in neonates. When prescribing BLINCYTO® (with preservative) for neonatal patients, consider the combined daily metabolic load of benzyl alcohol from all sources including BLINCYTO® (with preservative), other products containing benzyl alcohol or other excipients (e.g., ethanol, propylene glycol) which compete with benzyl alcohol for the same metabolic pathway.

  Monitor neonatal patients receiving BLINCYTO® (with preservative) for new or worsening metabolic acidosis. The minimum amount of benzyl alcohol at which serious adverse reactions may occur in neonates is not known. The BLINCYTO® 7-Day bag (with preservative) contains 7.4 mg of benzyl alcohol per mL.

- **Embryo-Fetal Toxicity:** Based on its mechanism of action, BLINCYTO® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with BLINCYTO® and for 48 hours after the last dose.

Adverse Reactions

- The safety of BLINCYTO® in adult and pediatric patients one month and older with MRD-positive B-cell precursor ALL (n=137), relapsed or refractory B-cell precursor ALL (n=267), and Philadelphia chromosome-negative B-cell precursor ALL in consolidation (n=165) was evaluated in clinical studies. The most common adverse reactions (≥ 20%) to BLINCYTO® in this pooled population were pyrexia, infusion-related reactions, headache, infection, musculoskeletal pain, neutropenia, nausea, anemia, thrombocytopenia, and diarrhea.

Dosage and Administration Guidelines

- BLINCYTO® is administered as a continuous intravenous infusion at a constant flow rate using an infusion pump which should be programmable, lockable, non-elastomeric, and have an alarm.
- It is very important that the instructions for preparation (including admixing) and administration provided in the full Prescribing Information are strictly followed to minimize medication errors (including underdose and overdose).

INDICATIONS

BLINCYTO® (blinatumomab) is indicated for the treatment of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients one month and older with:

- Philadelphia chromosome-negative disease in the consolidation phase of multiphase chemotherapy.
- Minimal residual disease (MRD) greater than or equal to 0.1% in first or second complete remission.
- Relapsed or refractory disease.

Please see BLINCYTO® full Prescribing Information, including BOXED WARNINGS.

About Bispecific T-Cell Engager (BiTE®) Technology

BiTE technology is a targeted immuno-oncology platform that is designed to engage a patient's own T cells to any tumor-specific antigen, activating the cytotoxic potential of T cells to eliminate detectable cancer. The BiTE immuno-oncology platform has the potential to treat different cancer types through tumor-specific antigens. The BiTE platform has a goal of leading to off-the-shelf solutions, which have the potential to make innovative T-cell treatment available to all providers when their patients need it. For more than a decade, Amgen has been advancing this innovative technology, which has demonstrated strong efficacy in hematological malignancies and now a solid tumor with the approval of IMDELLTRA. Amgen remains committed to progressing multiple BiTE molecules across a broad range of hematologic and solid tumor malignancies, paving the way for additional applications in more tumor types. Amgen is further investigating BiTE technology with the goal of enhancing patient experience and therapeutic potential. To learn more about BiTE technology, visit BiTE® Technology 101.

About Amgen

Amgen discovers, develops, manufactures and delivers innovative medicines to help millions of patients in their fight against some of the world's toughest diseases. More than 40 years ago, Amgen helped to establish the biotechnology industry and remains on the cutting-edge of innovation, using technology and human genetic data to push beyond what's known today. Amgen is advancing a broad and deep pipeline that builds on its existing portfolio of medicines to treat cancer, heart disease, osteoporosis, inflammatory diseases and rare diseases.

In 2024, Amgen was named one of the "World's Most Innovative Companies" by Fast Company and one of "America's Best Large Employers" by Forbes, among other external recognitions. Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average®, and it is also part of the Nasdaq-100 Index®, which includes the largest and most innovative non-financial companies listed on the Nasdaq Stock Market based on market capitalization.

For more information, visit Amgen.com and follow Amgen on X, LinkedIn, Instagram, TikTok, YouTube and Threads.

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 any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd. or Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), Amgen's acquisitions of Teneobio, Inc., ChemoCentryx, Inc., or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities, any potential strategic benefits, synergies or opportunities expected as a result of such acquisition, and any projected impacts from the Horizon acquisition on Amgen's acquisition-related expenses going forward), as well as 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, effects of pandemics or other widespread health problems on Amgen's business, outcomes, progress, 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 its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on 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 Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market.

Amgen's results may be affected by its 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 its products and global economic conditions. In addition, sales of Amgen's 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, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for Amgen's manufacturing activities, the distribution of Amgen's products, the commercialization of Amgen's product candidates, and Amgen's clinical trial operations, and any such events may have a material adverse effect on Amgen's product development, product sales, business and results of operations. Amgen relies on collaborations with third parties for the development of some of its product candidates and for the commercialization and sales of some of its commercial products. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology Amgen has acquired, may not be successful. There can be no guarantee that Amgen will be able to realize any of the strategic benefits, synergies or opportunities arising from the Horizon acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. Amgen may not be able to successfully integrate Horizon, and such integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach of Amgen's information technology systems could compromise the confidentiality, integrity and availability of Amgen's systems and Amgen's data. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business and operations may be negatively affected by the failure, or perceived failure, of achieving its environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect Amgen's business and operations. Global economic conditions may magnify certain risks that affect Amgen's business. Amgen's business performance could affect or limit the ability of

the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

Any scientific information discussed in this news release relating to new indications for Amgen's 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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