



Amgen To Showcase New Data From Oncology Portfolio At ASCO 2021

May 19, 2021

LUMAKRAS™ (Sotorasib)¹ Overall Survival and Biomarker Subgroup Analyses From Registrational Phase 2 CodeBreak 100 Trial in KRAS G12C-Mutated Non-Small Cell Lung Cancer New Data From the Phase 2 FIGHT Trial with Bemarituzumab in Advanced Gastric and Gastroesophageal Junction Cancers

THOUSAND OAKS, Calif., May 19, 2021 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that new data from its expanding oncology pipeline and marketed portfolio will be presented during the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting taking place virtually from June 4-8, 2021.

Overall survival (OS) data from the Phase 2 CodeBreak 100 trial of LUMAKRAS™ (sotorasib), a potentially first-in-class KRAS^{G12C} inhibitor in non-small cell lung cancer (NSCLC) will be presented for the first time alongside additional exploratory biomarker subgroup analyses in an oral presentation on Friday, June 4, 2021. Updated data for investigational bemarituzumab in combination with chemotherapy from the Phase 2 FIGHT trial will also be shared in an oral presentation on Friday, June 4, 2021, in patients with FGFR2b+ advanced gastric and gastroesophageal junction adenocarcinoma (GEJ).

"Precision medicine is paving the way to the future of cancer care, and Amgen continues to relentlessly pursue breakthroughs by exploring targeted treatment approaches in a diverse range of modalities for patients with difficult-to-treat cancers," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "With new data from across our oncology portfolio, we are proud to drive the advancement of the potential next generation of targeted cancer treatments for patients who need it most."

Additional research to be presented at ASCO includes updated safety and efficacy data from the first-in-human (FIH) study of AMG 757 (tarlatamab) in small cell lung cancer (SCLC). Tarlatamab is an investigational first-in-class half-life extended (HLE) bispecific T-cell engager (BiTE[®]) molecule that is uniquely designed to target delta-like ligand 3 (DLL3) in neuroendocrine cancers such as small cell lung cancer (SCLC) and neuroendocrine prostate cancer.

Investigator sponsored study (ISS) presentations include new oral data presentations from the PANAMA trial evaluating VECTIBIX[®] (panitumumab) in combination with 5-fluorouracil/leucovorin (5FU/LV) as maintenance therapy in metastatic colorectal cancer (mCRC), and new data from the CHRONOS trial evaluating anti-EGFR rechallenge therapy with Vectibix in mCRC.

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

Amgen Webcast Investor Call

Amgen will host a webcast call for the investment community in conjunction with ASCO on Friday, June 4, 2021 at 4:00 p.m. ET. David M. Reese, M.D., executive vice president of Research and Development at Amgen, along with members of Amgen's clinical development team will discuss clinical data being presented on the Company's investigational KRAS^{G12C} inhibitor LUMAKRAS™, anti-FGFR2b antibody bemarituzumab and DLL3-targeting HLE BiTE[®] tarlatamab.

Live audio of the conference call will be broadcast over the internet simultaneously 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 at certain investor and medical conferences, can be accessed 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.

Key Abstracts and Presentation Times:

LUMAKRAS

- **Overall Survival and Exploratory Subgroup Analyses From the Phase 2 CodeBreak100 Trial Evaluating Sotorasib in Pretreated KRAS p.G12C Mutated Non-Small Cell Lung Cancer**
Abstract #9003, Oral Presentation, Session: Lung Cancer—Non-Small Cell Metastatic, Friday, June 4 from 1:00 – 4:00 p.m. ET
- **Patient-Reported Outcomes (PRO) From the Phase 2 CodeBreak 100 Trial Evaluating Sotorasib in KRAS p.G12C Mutated Non-Small Cell Lung Cancer**
Abstract #9057, Poster, Session: Lung Cancer—Non-Small Cell Metastatic, Friday, June 4 at 9:00 a.m. ET
- **Trial-in-Progress: A Phase 1b Study of Sotorasib, A Specific and Irreversible KRAS G12C Inhibitor, as Monotherapy in Non-Small Cell Lung Cancer (NSCLC) with Brain Metastasis and in Combination with Other Anticancer Therapies in Advanced Solid Tumors (CodeBreak 101)**
Abstract #TPS2669, Poster, Session: Developmental Therapeutics—Immunotherapy, Friday, June 4 at 9:00 a.m. ET

Bemarituzumab

- **FIGHT: A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Bemarituzumab (Bema) Combined with**

Modified FOLFOX6 in 1L FGFR2b+ Advanced Gastric/Gastroesophageal Junction Adenocarcinoma (GC/GEJ)

Abstract #4010, Oral Presentation, Session: Biomarker-Driven Approaches for the Treatment of Gastrointestinal Cancers, Friday, June 4 at 9:00 a.m. ET

AMG 757 (Tarlatab)

- **Updated Results from a Phase 1 Study of AMG 757 (Tarlatab), a Half-Life Extended Bispecific T-Cell Engager (BiTE) Immuno-Oncology Therapy Against Delta-Like Ligand 3 (DLL3), in Small-Cell Lung Cancer (SCLC)**
Abstract #8510, Poster Discussion, Session: Lung Cancer—Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers, Friday, June 4 at 9:00 a.m. ET
- **Trial-in-Progress: A Phase 1b Study of AMG 757 (Tarlatab) in Subjects with Neuroendocrine Prostate Cancer**
Abstract #TPS5100, Poster, Session: Genitourinary Cancer—Prostate, Testicular, and Penile, Friday, June 4 at 9:00 a.m. ET

AMG 160 (Acapatamab)

- **Trial-in-Progress: Safety and Efficacy of AMG 160 Half-Life Extended BiTE® Immune Therapy Targeting Prostate-Specific Membrane Antigen (PSMA) and Other Therapies for Metastatic Castration-Resistant Prostate Cancer (mCRPC)**
Abstract #TPS5088, Poster, Session: Genitourinary Cancer—Prostate, Testicular, and Penile, Friday, June 4 at 9:00 a.m. ET

AMG 650

- **Trial-in-Progress: A Phase 1, Multicenter, Open-Label, Dose-Exploration and Dose-Expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 650 in Subjects with Advanced Solid Tumors**
Abstract #TPS5600, Poster, Session: Gynecologic Cancer, Friday, June 4 at 9:00 a.m. ET

BLINCYTO® (blinatumomab)

- **Trial-in-Progress: A Phase 4 Study to Evaluate Outpatient Blinatumomab in Patients with Minimal/Measurable Residual Disease (MRD) of B-cell Precursor Acute Lymphoblastic Leukemia (BCP-ALL)**
Abstract #TPS7051, Poster, Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant, Friday, June 4 at 9:00 a.m. ET

IMLYGIC® (talimogene laherparepvec)

- **Final Analysis of a Phase 1b, Randomized, Multicenter Study of Talimogene Laherparepvec (T-VEC) Plus Pembrolizumab (Pembro) Combination for the Treatment of Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck (R/M HNSCC): MASTERKEY-232**
Abstract #6036, Poster, Session: Head and Neck Cancer, Friday, June 4 at 9:00 a.m. ET

VECTIBIX® (panitumumab)

- **Rarity of Acquired Mutations (MTs) after First-Line Therapy with Anti-EGFR Therapy (EGFRi)**
Abstract #3514, Poster Discussion, Session: Gastrointestinal Cancer—Colorectal and Anal, Friday, June 4 at 9:00 a.m. ET

Investigator Sponsored Studies (ISS)

- **Maintenance Therapy with 5-Fluorouracil/Leucovorin (5FU/LV) Plus Panitumumab (pmab) or 5FU/LV Alone in RAS Wildtype (WT) Metastatic Colorectal Cancer (mCRC) - The PANAMA Trial (AIO KRK 0212)**
Abstract #3503, Oral Presentation, Session: Gastrointestinal Cancer—Colorectal and Anal, Monday, June 7, 1:15 – 4:15 p.m. ET
- **Phase II Study of Anti-EGFR Rechallenge Therapy with Panitumumab Driven by Circulating Tumor DNA Molecular Selection in Metastatic Colorectal Cancer: The CHRONOS Trial**
Abstract #3506, Oral Presentation, Session: Gastrointestinal Cancer—Colorectal and Anal, Monday, June 7, 1:15 – 4:15 p.m. ET

XGEVA® (denosumab)

- **Risk Factors Associated with Skeletal-Related Events Following Denosumab Cessation Among Patients with Bone Metastases from Solid Tumors: A Real-World Machine Learning Approach**
Abstract #1567, Poster, Session: Care Delivery and Regulatory Policy, Friday, June 4 at 9:00 a.m. ET

Learn more about Amgen's development of innovative medicines for novel targets in difficult-to-treat solid tumors at [AmgenOncology.com](https://www.amgen.com/oncology)

About LUMAKRAS™ (sotorasib)

Amgen has taken on one of the toughest challenges of the last 40 years in cancer research by developing LUMAKRAS, an investigational KRAS^{G12C} inhibitor.² LUMAKRAS was the first KRAS^{G12C} inhibitor to enter the clinic and is being studied in the largest clinical program exploring 11 combinations with global sites spanning five continents. In just under three years from first patient dosed, the LUMAKRAS clinical program CodeBreak has established the deepest clinical data set with more than 800 patients studied across 13 tumor types.

LUMAKRAS has demonstrated a positive benefit-risk profile with fast, deep and durable anticancer activity in patients with advanced non-small cell lung cancer (NSCLC) harboring the *KRAS* G12C mutation with a once daily oral formulation. LUMAKRAS is also being studied in multiple other solid tumors.^{2,3}

About CodeBreak

The CodeBreak clinical development program for Amgen's drug sotorasib is designed to treat patients with an advanced solid tumor with the *KRAS* G12C mutation and address the longstanding unmet medical need for these cancers. As the most advanced *KRAS* G12C clinical development program, CodeBreak has enrolled more than 800 patients across 13 tumor types since its inception.

CodeBreak 100, the Phase 1 and 2, first-in-human, open-label multicenter study, enrolled patients with *KRAS* G12C-mutant solid tumors. Eligible patients must have received a prior line of systemic anticancer therapy, consistent with their tumor type and stage of disease. The primary endpoint for the Phase 2 study was centrally assessed objective response rate. The Phase 2 trial in NSCLC enrolled 126 patients, 124 of whom had centrally evaluable lesions by RECIST at baseline. The Phase 2 trial in colorectal cancer (CRC) is fully enrolled and topline results are expected in 2021.

A global Phase 3 randomized active-controlled study comparing sotorasib to docetaxel in *KRAS* G12C-mutated NSCLC patients (CodeBreak 200) completed enrollment in April 2021. Amgen has several Phase 1b combination studies across various advanced solid tumors (CodeBreak 101) open for enrollment.

About Bemarituzumab

Bemarituzumab (anti-FGFR2b) is a potential first-in-class investigational targeted antibody that is designed to block specific fibroblast growth factors (FGFs) from binding and activating FGFR2b, inhibiting several downstream pro-tumor signaling pathways and potentially slowing cancer progression. Bemarituzumab is being developed in gastric and GEJ cancer as a targeted therapy for tumors that overexpress FGFR2b. The company is also evaluating the potential for bemarituzumab in other cancers that overexpress FGFR2b. In April 2021, bemarituzumab was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration.

Zai Lab (Shanghai) Co. Ltd. was granted an exclusive license to develop and commercialize bemarituzumab in Greater China, and Zai Lab collaborated with Five Prime on the Phase 2 FIGHT trial in Greater China.

About BiTE® Technology

BiTE® (bispecific T cell engager) 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 tumor 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. Amgen is advancing BiTE molecules across a broad range of hematologic malignancies and solid tumors and further investigating BiTE technology with the goal of enhancing patient experience and therapeutic potential.

About BLINCYTO® (Blinatumomab)

BLINCYTO is a BiTE® (bispecific T-cell engager) 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. Food and Drug Administration and is approved in the U.S. for the treatment of:

- relapsed or refractory CD-19 positive B-cell precursor ALL in adults and children.
- CD-19 positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children. This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

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-precursor acute lymphoblastic leukaemia (ALL).
- adults with Philadelphia chromosome negative CD19 positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.
- paediatric patients aged 1 year or older with Philadelphia chromosome negative CD19 positive B-precursor 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

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGICAL TOXICITIES

- **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, 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 15% of patients with R/R ALL and in 7% of patients with MRD-positive ALL. 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, and hemophagocytic histiocytosis/macrophage activation syndrome. 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:** Approximately 65% of patients receiving BLINCYTO® in clinical trials experienced neurological toxicities. The median time to the first event was within the first 2 weeks of BLINCYTO® treatment and the majority of events resolved. The most common ($\geq 10\%$) manifestations of neurological toxicity were headache and tremor. Severe, life-threatening, or fatal 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. Monitor patients for signs or symptoms and interrupt or discontinue BLINCYTO® as outlined in the PI.
- **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, 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 TBILI 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 TBILI 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[®].

- Risk of Serious Adverse Reactions in Pediatric Patients due to Benzyl Alcohol Preservative: Serious and fatal adverse reactions including "gaspings syndrome," which is characterized by central nervous system depression, metabolic acidosis, and gasping respirations, can occur in neonates and infants treated with benzyl alcohol-preserved drugs including BLINCYTO[®] (with preservative). When prescribing BLINCYTO[®] (with preservative) for pediatric patients, consider the combined daily metabolic load of benzyl alcohol from all sources including BLINCYTO[®] (with preservative) and other drugs containing benzyl alcohol. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known. Due to the addition of bacteriostatic saline, 7-day bags of BLINCYTO[®] solution for infusion with preservative contain benzyl alcohol and are not recommended for use in any patients weighing < 22 kg.

Adverse Reactions

- The most common adverse reactions (≥ 20%) in clinical trial experience of patients with MRD-positive B-cell precursor ALL (BLAST Study) treated with BLINCYTO[®] were pyrexia (91%), infusion-related reactions (77%), headache (39%), infections (pathogen unspecified 39%), tremor (31%), and chills (28%). Serious adverse reactions were reported in 61% of patients. The most common serious adverse reactions (≥ 2%) included pyrexia, tremor, encephalopathy, aphasia, lymphopenia, neutropenia, overdose, device related infection, seizure, and staphylococcal infection.
- The most common adverse reactions (≥ 20%) in clinical trial experience of patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL (TOWER Study) treated with BLINCYTO[®] were infections (bacterial and pathogen unspecified), pyrexia, headache, infusion-related reactions, anemia, febrile neutropenia, thrombocytopenia, and neutropenia. Serious adverse reactions were reported in 62% of patients. The most common serious adverse reactions (≥ 2%) included febrile neutropenia, pyrexia, sepsis, pneumonia, overdose, septic shock, CRS, bacterial sepsis, device related infection, and bacteremia.
- Adverse reactions that were observed more frequently (≥ 10%) in the pediatric population compared to the adults with relapsed or refractory B-cell precursor ALL were pyrexia (80% vs. 61%), hypertension (26% vs. 8%), anemia (41% vs. 24%), infusion-related reaction (49% vs. 34%), thrombocytopenia (34% vs. 21%), leukopenia (24% vs. 11%), and weight increased (17% vs. 6%).
- In pediatric patients less than 2 years old (infants), the incidence of neurologic toxicities was not significantly different than for the other age groups, but its manifestations were different; the only event terms reported were agitation, headache, insomnia, somnolence, and irritability. Infants also had an increased incidence of hypokalemia (50%) compared to other pediatric age cohorts (15-20%) or adults (17%).

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).

Please see full Prescribing Information and medication guide for BLINCYTO at www.BLINCYTO.com.

About IMLYGIC[®] (talimogene laherparepvec)

IMLYGIC is a genetically modified herpes simplex type 1 virus that is injected directly into tumors. IMLYGIC replicates inside tumor cells and produces GM-CSF, an immunostimulatory protein. IMLYGIC then causes the cell to rupture and die in a process called lysis. The rupture of the cancer cells causes the release of tumor-derived antigens, which together with virally derived GM-CSF may help to promote an anti-tumor immune response. The exact mechanism of action continues to be investigated.

IMLYGIC is the first and only oncolytic viral therapy approved by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other regulatory authorities, based on therapeutic benefit demonstrated in a pivotal Phase 3 study. IMLYGIC is indicated for the local treatment of melanoma in patients with unresectable cutaneous, subcutaneous, or nodal lesions after initial surgery.

The IMLYGIC clinical program continues to investigate the role of IMLYGIC both as monotherapy and in combination with other therapies across a variety of cancers and treatment settings.

INDICATION & LIMITATIONS OF USE

IMLYGIC[®] (talimogene laherparepvec) is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

Limitations of use: IMLYGIC[®] has not been shown to improve overall survival or have an effect on visceral metastases.

IMPORTANT SAFETY INFORMATION

Contraindications

- Do not administer IMLYGIC[®] to immunocompromised patients, including those with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human

immunodeficiency viruses, and those on immunosuppressive therapy, due to the risk of life-threatening disseminated herpetic infection.

- Do not administer IMLYGIC[®] to pregnant patients.

Warnings and Precautions

- Accidental exposure to IMLYGIC[®] may lead to transmission of IMLYGIC[®] and herpetic infection, including during preparation and administration. Health care providers, close contacts, pregnant women, and newborns should avoid direct contact with injected lesions, dressings, or body fluids of treated patients. The affected area in exposed individuals should be cleaned thoroughly with soap and water and/or a disinfectant.
- Caregivers should wear protective gloves when assisting patients in applying or changing occlusive dressings and observe safety precautions for disposal of used dressings, gloves, and cleaning materials. Exposed individuals should clean the affected area thoroughly with soap and water and/or a disinfectant.
- To prevent possible inadvertent transfer of IMLYGIC[®] to other areas of the body, patients should be advised to avoid touching or scratching injection sites or occlusive dressings.
- Herpetic infections: Herpetic infections (including cold sores and herpetic keratitis) have been reported in IMLYGIC[®]-treated patients. Disseminated herpetic infection may also occur in immunocompromised patients. Patients who develop suspicious herpes-like lesions should follow standard hygienic practices to prevent viral transmission.
- Patients or close contacts with suspected signs or symptoms of a herpetic infection should contact their health care provider to evaluate the lesions. Suspected herpetic lesions should be reported to Amgen at 1-855-IMLYGIC (1-855-465-9442). Patients or close contacts have the option of follow-up testing for further characterization of the infection.
- IMLYGIC[®] is sensitive to acyclovir. Acyclovir or other antiviral agents may interfere with the effectiveness of IMLYGIC[®]. Consider the risks and benefits of IMLYGIC[®] treatment before administering antiviral agents to manage herpetic infection.
- Injection Site Complications: Necrosis or ulceration of tumor tissue may occur during IMLYGIC[®] treatment. Cellulitis and systemic bacterial infection have been reported in clinical studies. Careful wound care and infection precautions are recommended, particularly if tissue necrosis results in open wounds.
- Impaired healing at the injection site has been reported. IMLYGIC[®] may increase the risk of impaired healing in patients with underlying risk factors (e.g., previous radiation at the injection site or lesions in poorly vascularized areas). If there is persistent infection or delayed healing of the injection site, consider the risks and benefits of continuing treatment.
- Immune-Mediated events including glomerulonephritis, vasculitis, pneumonitis, worsening psoriasis, and vitiligo have been reported in patients treated with IMLYGIC[®]. Consider the risks and benefits of IMLYGIC[®] before initiating treatment in patients who have underlying autoimmune disease or before continuing treatment in patients who develop immune-mediated events.
- Plasmacytoma at the Injection Site: Plasmacytoma in proximity to the injection site has been reported in a patient with smoldering multiple myeloma after IMLYGIC[®] administration in a clinical study. Consider the risks and benefits of IMLYGIC[®] in patients with multiple myeloma or in whom plasmacytoma develops during treatment.
- Obstructive Airway Disorder: Obstructive airway disorder has been reported following IMLYGIC[®] treatment. Use caution when injecting lesions close to major airways.

Adverse Reactions

- The most commonly reported adverse drug reactions ($\geq 25\%$) in IMLYGIC[®]-treated patients were fatigue, chills, pyrexia, nausea, influenza-like illness, and injection site pain. Pyrexia, chills, and influenza-like illness can occur at any time during IMLYGIC[®] treatment, but were more frequent during the first 3 months of treatment.
- The most common Grade 3 or higher adverse reaction was cellulitis.

Please see www.lmlygic.com for full Prescribing Information, including Medication Guide.

About Vectibix[®] (panitumumab)

Vectibix is the first fully human monoclonal 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.

In June 2017, the FDA approved a refined indication for Vectibix for use in patients with wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) mCRC.

INDICATION AND LIMITATION OF USE

Vectibix[®] is indicated for the treatment of patients with wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC): as first-line therapy in combination with FOLFOX, and as monotherapy

following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.

Limitation of Use: Vectibix[®] is not indicated for the treatment of patients with RASmutant mCRC or for whom RAS mutation status is unknown.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: DERMATOLOGIC TOXICITY

Dermatologic Toxicity: Dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients receiving Vectibix monotherapy [see *Dosage and Administration* (2.3), *Warnings and Precautions* (5.1), and *Adverse Reactions* (6.1)].

- In Study 20020408, dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients with mCRC receiving Vectibix[®]. The clinical manifestations included, but were not limited to, acneiform dermatitis, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures.
- Monitor patients who develop dermatologic or soft tissue toxicities while receiving Vectibix[®] for the development of inflammatory or infectious sequelae. Life-threatening and fatal infectious complications including necrotizing fasciitis, abscesses, and sepsis have been observed in patients treated with Vectibix[®]. Life-threatening and fatal bullous mucocutaneous disease with blisters, erosions, and skin sloughing has also been observed in patients treated with Vectibix[®]. It could not be determined whether these mucocutaneous adverse reactions were directly related to EGFR inhibition or to idiosyncratic immune-related effects (e.g., Stevens Johnson syndrome or toxic epidermal necrolysis). Withhold or discontinue Vectibix[®] for dermatologic or soft tissue toxicity associated with severe or life-threatening inflammatory or infectious complications. Dose modifications for Vectibix[®] concerning dermatologic toxicity are provided in the product labeling.
- Vectibix[®] is not indicated for the treatment of patients with colorectal cancer that harbor somatic RAS mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either KRAS or NRAS and hereafter is referred to as "RAS."
- Retrospective subset analyses across several randomized clinical trials were conducted to investigate the role of RAS mutations on the clinical effects of anti-EGFR-directed monoclonal antibodies (panitumumab or cetuximab). Anti-EGFR antibodies in patients with tumors containing RAS mutations resulted in exposing those patients to anti-EGFR related adverse reactions without clinical benefit from these agents. Additionally, in Study 20050203, 272 patients with RAS-mutant mCRC tumors received Vectibix[®] in combination with FOLFOX and 276 patients received FOLFOX alone. In an exploratory subgroup analysis, OS was shorter (HR = 1.21, 95% CI: 1.01-1.45) in patients with RAS-mutant mCRC who received Vectibix[®] and FOLFOX versus FOLFOX alone.
- Progressively decreasing serum magnesium levels leading to severe (grade 3-4) hypomagnesemia occurred in up to 7% (in Study 20080763) 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. Other electrolyte disturbances, including hypokalemia, have also been observed. Replete magnesium and other electrolytes as appropriate.
- In Study 20020408, 4% of patients experienced infusion reactions and 1% of patients experienced severe infusion reactions (NCI-CTC grade 3-4). Infusion reactions, manifesting as fever, chills, dyspnea, bronchospasm, and hypotension, can occur following Vectibix[®] administration. Fatal infusion reactions occurred in postmarketing experience. Terminate the infusion for severe infusion reactions.
- 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 nonfatal 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.
- In patients with a history of interstitial pneumonitis or pulmonary fibrosis, or evidence of interstitial pneumonitis or pulmonary fibrosis, the benefits of therapy with Vectibix[®] versus the risk of pulmonary complications must be carefully considered.
- Exposure to sunlight can exacerbate dermatologic toxicity. Advise patients to wear sunscreen and hats and limit sun exposure while receiving Vectibix[®].
- Keratitis and ulcerative keratitis, known risk factors for corneal perforation, have been reported with Vectibix[®] use. Monitor for evidence of keratitis or ulcerative keratitis. Interrupt or discontinue Vectibix[®] for acute or worsening keratitis.
- In an interim analysis of an open-label, multicenter, randomized clinical trial in the first-line setting in patients with mCRC, the addition of Vectibix[®] to the combination of bevacizumab and chemotherapy resulted in decreased OS and increased incidence of NCI-CTC grade 3-5 (87% vs 72%) adverse reactions. NCI-CTC grade 3-4 adverse reactions occurring at a higher rate in Vectibix[®]-treated patients included rash/acneiform dermatitis (26% vs 1%), diarrhea (23% vs 12%), dehydration (16% vs 5%), primarily occurring in patients with diarrhea, hypokalemia (10% vs 4%), stomatitis/mucositis (4%

vs < 1%), and hypomagnesemia (4% vs 0).

- NCI-CTC grade 3-5 pulmonary embolism occurred at a higher rate in Vectibix[®]-treated patients (7% vs 3%) and included fatal events in three (< 1%) Vectibix[®]-treated patients. As a result of the toxicities experienced, patients randomized to Vectibix[®], bevacizumab, and chemotherapy received a lower mean relative dose intensity of each chemotherapeutic agent (oxaliplatin, irinotecan, bolus 5-FU, and/or infusional 5-FU) over the first 24 weeks on study compared with those randomized to bevacizumab and chemotherapy.
- Vectibix[®] can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment, and for at least 2 months after the last dose of Vectibix[®].
- In monotherapy, the most commonly reported adverse reactions (≥ 20%) in patients with Vectibix[®] were skin rash with variable presentations, paronychia, fatigue, nausea, and diarrhea.
- The most commonly reported adverse reactions (≥ 20%) with Vectibix[®] + FOLFOX were diarrhea, stomatitis, mucosal inflammation, asthenia, paronychia, anorexia, hypomagnesemia, hypokalemia, rash, acneiform dermatitis, pruritus, and dry skin. The most common serious adverse reactions (≥ 2% difference between treatment arms) were diarrhea and dehydration.

To see the Vectibix[®] Prescribing Information, including Boxed Warning visit www.vectibix.com.

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 skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. XGEVA is also indicated 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 and for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

INDICATIONS

XGEVA[®] is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. XGEVA[®] is indicated 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 indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

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[®]. Reactions may include hypotension, dyspnea, upper airway edema, lip swelling, rash, pruritus, and urticaria. 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 been reported 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 cancer, 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 corticosteroids, 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. Any patient who presents with thigh or groin pain should be suspected of having an atypical fracture and should be evaluated to rule out an incomplete femur fracture. Patients 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.

Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone (GCTB) and in Patients with Growing Skeletons

Clinically significant hypercalcemia requiring hospitalization and complicated by acute renal injury has been reported in XGEVA[®]-treated patients with GCTB and in patients with growing skeletons within one year of treatment discontinuation. Monitor patients for signs and symptoms of hypercalcemia after treatment discontinuation and treat appropriately.

Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation

Multiple vertebral fractures (MVF) have been reported following discontinuation of treatment with denosumab. Patients at higher risk for MVF include those with risk factors for or a history of osteoporosis or prior fractures. When XGEVA[®] treatment is discontinued, evaluate the individual patient's risk for vertebral fractures.

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 effective contraception during therapy, and for at least 5 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 resulting in discontinuation were osteonecrosis and hypocalcemia.

For multiple myeloma patients receiving XGEVA[®], the most common adverse reactions were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache. The most common serious adverse reaction was pneumonia. The most common adverse reaction resulting in discontinuation of XGEVA[®] was osteonecrosis of the jaw.

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.

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

About Amgen Oncology

At Amgen Oncology, our mission to serve patients drives all that we do. That's why we're relentlessly focused on accelerating the delivery of medicines that have the potential to empower all angles of care and transform lives of people with cancer.

For the last four decades, we have been dedicated to discovering the firsts that matter in oncology and to finding ways to reduce the burden of cancer. Building on our heritage, Amgen continues to advance the largest pipeline in the Company's history, moving with great speed to advance those innovations for the patients who need them.

At Amgen, we're advancing oncology at the speed of life™.

For more information, follow us on www.twitter.com/amgenoncology.

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 any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd. or any collaboration to manufacture therapeutic antibodies against COVID-19), the integration of Otezla® (apremilast) into our business (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), or the Five Prime Therapeutics, Inc. acquisition, 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 such as the ongoing COVID-19 pandemic on our business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, 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 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 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, including our devices, 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. 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, including in Puerto Rico, 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. 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 our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. 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 collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Global economic conditions may magnify certain risks that affect our business. 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. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

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, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Further, any 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.

CONTACT: Amgen, Thousand Oaks
Megan Fox, 805-447-1423 (media)
Arvind Sood, 805-447-1060 (investors)

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