AMGEN TO PRESENT NEW RESEARCH FROM ONCOLOGY PORTFOLIO AND PIPELINE AT ESMO 2023

October 16, 2023

Results From Phase 2 DeLLphi-301 Trial Highlight Potential of Tarlatamab, First BiTE in Patients With Previously Treated SCLC

Pivotal Phase 3 CodeBreaK 300 Study Data Support LUMAKRAS® (sotorasib) Plus Vectibix® (panitumumab) Combination in *KRAS* G12C-Mutated mCRC

Early-Stage Results for AMG 509 (xaluritamig) Illustrate Expanding Potential of Amgen's T-Cell Engagers in mCRPC

THOUSAND OAKS, Calif., Oct. 16, 2023 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the presentation of new data across its broad oncology portfolio and pipeline at the European Society for Medical Oncology (ESMO) Congress 2023, taking place from October 20-24 in Madrid. Results from Amgen-sponsored and collaborative studies, including two late-breaking oral presentations, will feature data in a range of tough-to-treat cancers.

"Our data at ESMO demonstrate the rapid progress we are making in advancing a portfolio with first-in-class therapies, including metastatic *KRAS* G12C mutated colorectal cancer and small cell lung cancer," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "These findings illustrate how we are attacking cancer from many different angles to deliver new approaches poised to alter the natural history of disease across many cancers."

Amgen will present data from two late-breaking abstracts at ESMO:

- Results from CodeBreaK 300 (Abstract #LBA10), a global, registration-enabling Phase 3 trial evaluating LUMAKRAS (sotorasib) combined with Vectibix (panitumumab) in chemorefractory *KRAS* G12C-mutated metastatic CRC. These data will be featured as a Presidential Symposium Oral Presentation on Sunday, October 22.
- Results from DeLLphi-301 (Abstract #LBA92), a global, potentially registration-enabling Phase 2 trial evaluating tarlatamab, a first-in-class DLL3 targeting bispecific T-cell engager (BiTE®) molecule, in patients with SCLC who had failed two or more prior lines of treatment. These data will be presented in a Proffered Paper Oral Session on Friday, October 20.

Interim results from a Phase 1 study of AMG 509 (xaluritamig) will be presented during a Proffered Paper Oral Session (Abstract #1765O), demonstrating that the novel bispecific STEAP1 x CD3 XmAb® 2+1 T-cell engager had a positive benefit/risk profile with robust anti-tumor activity in heavily pretreated patients with mCRPC (N=97). Overall, of the 67 RECIST-evaluable patients, 16 (24%) had confirmed partial responses (PR) and 32 (48%) had stable disease (SD), demonstrating encouraging preliminary efficacy. At higher dosing levels (n=37), 15 patients (41%) had confirmed PR and 14 (38%) with SD. The most common treatment-related adverse events were cytokine release syndrome (CRS; 72%; primarily low grade), fatigue (45%), myalgia (34%) and pyrexia (32%).

These results further justify exploration of this modality as a potential therapy for prostate cancer. Dose expansion and optimization are currently ongoing.

For more information on the Amgen abstracts, see below.

Abstracts and Presentation Times:

Amgen Sponsored Abstracts

LUMAKRAS®/LUMYKRAS® (sotorasib) + VECTIBIX® (panitumumab) for CRC

- **Sotorasib plus panitumumab versus standard-of-care for chemorefractory *KRAS* G12C-mutated metastatic colorectal cancer (mCRC): CodeBreaK 300 phase 3 study**
  Abstract #LBA10, Proffered Paper Oral Session: Presidential 2, Madrid Auditorium - Hall 6, Sunday, October 22 from 5:50 - 6:02 p.m. CEST

Tarlatamab

- **Tarlatamab for patients (pts) with previously treated small cell lung cancer (SCLC): Primary analysis of the phase 2 DeLLphi-301 study**
  Abstract #LBA92, Proffered Paper Oral Session: Non metastatic NSCLC and other thoracic malignancies, Sevilla Auditorium - Hall 9, Friday, October 20 from 3:20 – 3:30 p.m. CEST

AMG 509 (xaluritamig)

- **Interim Results From a Phase 1 Study of AMG 509 (xaluritamig), a STEAP1 x CD3 XmAb® 2+1 Immune Therapy, in Patients With Metastatic Castration-Resistant Prostate Cancer (mCRPC)**
  Abstract #1765O, Proffered Paper Oral Session: Genitourinary tumours, prostate, Granada Auditorium - Hall 3, Friday,

October 20 from 4:10 - 4:20 p.m. CEST

Bemarituzumab

- **Phase 1b Results of Bemarituzumab (BEMA)+mFOLFOX6+Nivolumab (NIVO) for Advanced Gastric/Gastroesophageal Junction Cancer (G/GEJC): FORTITUDE-102 Part 1**
  Abstract #1526P, Onsite Poster, Monday, October 23

LUMAKRAS®/LUMYKRAS® (sotorasib) for Non-Small Cell Lung Cancer (NSCLC)

- **Real-world routine *KRAS* testing practices in France for patients (pts) with advanced or metastatic (AM) Non-Small Cell Lung Cancer (NSCLC): data from the ESME cohort**
  Abstract #1402P, Onsite Poster, Monday, October 23
- **Clinical characteristics and therapeutics sequences of *KRAS* G12C metastatic Non-Small Cell Lung Cancer (mNSCLC) patients treated by sotorasib in the French pre-marketing authorization (MA) early access program (cohort temporary authorization of use, cATU)**
  Abstract #1404P, Onsite Poster, Monday, October 23
- **Characteristics and treatment sequences of patients (pts) with *KRAS* G12C, other *KRAS* and non-*KRAS* advanced or metastatic (AM) Non-Small Cell Lung Cancer (NSCLC) in the French ESME cohort**
  Abstract #1407P, Onsite Poster, Monday, October 23
- **Characterization of patients with advanced non-small-cell lung cancer (NSCLC) harboring KRASG12C mutation and their associated direct healthcare costs in Spanish routine clinical practice (SILK study)**
  Abstract #1410P, Onsite Poster, Monday, October 23

Investigator Sponsored Studies

VECTIBIX® (panitumumab)

- **Panitumumab (P) + FOLFIRINOX or mFOLFOX6 in unresectable metastatic colorectal cancer (mCRC) patients (pts) with RAS/BRAF wild-type (WT) tumor status from circulating DNA (cirDNA). First results of the randomised phase II PANIRINOX-UCGI28 study**
  Abstract #LBA30, Mini oral session: Gastrointestinal tumours, lower digestive, Sunday, October 22 from 2:45 – 2:50 p.m. CEST
- **FOxTROT: results of embedded phase II evaluating the addition of panitumumab (pan) to neo-adjuvant FOLFOX for patients (pts) with *KRAS*-wt colon cancer (CC) with extended biomarker panel**
  Abstract #552O, Proffered Paper Oral Session 2: Gastrointestinal tumours, lower digestive, Barcelona Auditorium - Hall 9, Monday, October 23 from 8:30 – 8:40 a.m. CEST
- **Evaluation of the metastatic colorectal cancer score (mCCS) in predicting outcome for patients with *RAS* wild type metastatic colorectal cancer (mCRC) treated with first-line (1L) panitumumab (PAN) plus FOLFIRI/FOLFOX: Updated interim results of the non-interventional study VALIDATE**
  Abstract #622P, Onsite Poster, Sunday, October 22

XGEVA® (denosumab)

- **Results of the window-of-opportunity clinical trial D-BIOMARK: Study of biomarkers of the antitumor activity of denosumab and its role as a modulator of the immune response in early breast cancer**
  Abstract #289P, Onsite Poster, Saturday, October 21
- **Pembrolizumab and Denosumab in clear cell renal cell carcinoma (ccRCC): a phase 2 trial (KeyPAD, ANZUP1601)**
  Abstract #1886P, Onsite Poster, Monday, October 23

*XmAb® is a registered trademark of Xencor, Inc.

About LUMAKRAS®/LUMYKRAS® (sotorasib)
LUMAKRAS received accelerated approval from the U.S. Food and Drug Administration on May 28, 2021. The Supplemental New Drug Application (sNDA) for full approval of LUMAKRAS was accepted by the FDA for standard review and a Prescription Drug User Fee Act (PDUFA) target action date of December 24, 2023, has been set.

About Advanced Colorectal Cancer and the *KRAS* G12C Mutation
Colorectal cancer (CRC) is the second leading cause of cancer deaths worldwide, comprising 10% of all cancer diagnoses.[1] It is also the third most commonly diagnosed cancer globally.[2]

Patients with previously treated metastatic CRC need more effective treatment options. For patients in the third-line setting, standard therapies yield median progression-free survival (PFS) times of about two months, and patients' response rates are less than 10%.[3]

KRAS mutations are among the most common genetic alterations in colorectal cancers, with the *KRAS* G12C mutation present in approximately 3-5%

of colorectal cancers.[4,5,6]

About CodeBreaK
The CodeBreaK clinical development program for Amgen's drug sotorasib is designed to study patients with an advanced solid tumor with the *KRAS* G12C mutation and address the longstanding unmet medical need for these cancers.

CodeBreaK 100, the Phase 1 and 2, first-in-human, open-label multicenter study, enrolled patients with *KRAS* G12C-mutant solid tumors.[7] Eligible patients must have received at least 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 non-small cell lung cancer (NSCLC) enrolled 126 patients, 124 of whom had centrally evaluable lesions by RECIST at baseline.[8] The Phase 2 trial in colorectal cancer (CRC) enrolled 62 patients and results have been published.[9]

CodeBreaK 200, the global Phase 3 randomized active-controlled study comparing sotorasib to docetaxel in *KRAS* G12C-mutated NSCLC, completed enrollment of 345 patients. Eligible patients had previously treated, locally advanced and unresectable or metastatic *KRAS* G12C-mutated NSCLC. The primary endpoint is progression-free survival and key secondary endpoints include overall survival, objective response rate, and patient-reported outcomes.[10]

CodeBreaK 300, the global Phase 3 randomized active-controlled study comparing sotorasib in combination with panitumumab to investigator's choice (trifluridine and tipiracil, or regorafenib) in chemorefractory *KRAS* G12C-mutated mCRC, has completed enrollment of 160 patients. Eligible patients had *KRAS* G12C-mutated mCRC, received at least one prior line of therapy, and have received and progressed on or after fluoropyrimidine, irinotecan, and oxaliplatin. The primary endpoint is progression-free survival, and key secondary endpoints include overall survival (OS) and objective response rate (ORR).[11]

Amgen also has several Phase 1b studies investigating sotorasib monotherapy and sotorasib combination therapy across various advanced solid tumors (CodeBreaK 101) open for enrollment.[12] A Phase 2 randomized study evaluating sotorasib in patients with stage IV *KRAS* G12C-mutated NSCLC in need of first-line treatment is ongoing (CodeBreaK 201).[13] Amgen has also initiated a Phase 3 study of LUMAKRAS plus carboplatin and pemetrexed in first-line *KRAS* G12C-mutant and negative for programmed cell death PD-L1 advanced NSCLC (CodeBreaK 202), with enrollment expected to start before the end of 2023.

LUMAKRAS® (sotorasib) U.S. Indication
LUMAKRAS is indicated for the treatment of adult patients with *KRAS* G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

LUMAKRAS® (sotorasib) Important U.S. Safety Information

Hepatotoxicity

- LUMAKRAS can cause hepatotoxicity, which may lead to drug-induced liver injury and hepatitis.
- Among 357 patients who received LUMAKRAS in CodeBreaK 100, hepatotoxicity occurred in 1.7% (all grades) and 1.4% (Grade 3). A total of 18% of patients who received LUMAKRAS had increased alanine aminotransferase (ALT)/increased aspartate aminotransferase (AST); 6% were Grade 3 and 0.6% were Grade 4. In addition to dose interruption or reduction, 5% of patients received corticosteroids for the treatment of hepatotoxicity.
- Monitor liver function tests (ALT, AST and total bilirubin) prior to the start of LUMAKRAS every 3 weeks for the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop transaminase and/or bilirubin elevations.
- Withhold, dose reduce or permanently discontinue LUMAKRAS based on severity of adverse reaction.

Interstitial Lung Disease (ILD)/Pneumonitis

- LUMAKRAS can cause ILD/pneumonitis that can be fatal. Among 357 patients who received LUMAKRAS in CodeBreaK 100, ILD/pneumonitis occurred in 0.8% of patients, all cases were Grade 3 or 4 at onset, and 1 case was fatal. LUMAKRAS was discontinued due to ILD/pneumonitis in 0.6% of patients.
- Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold LUMAKRAS in patients with suspected ILD/pneumonitis and permanently discontinue LUMAKRAS if no other potential causes of ILD/pneumonitis are identified.

Most Common Adverse Reactions

- The most common adverse reactions occurring in ≥ 20% were diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity and cough.

Drug Interactions

- Advise patients to inform their healthcare provider of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, dietary and herbal products.
- Inform patients to avoid proton pump inhibitors and H_2 receptor antagonists while taking LUMAKRAS.

- If coadministration with an acid-reducing agent cannot be avoided, inform patients to take LUMAKRAS 4 hours before or 10 hours after a locally acting antacid.

Please see LUMAKRAS full Prescribing Information.

About Vectibix® (panitumumab)
Vectibix is the first and only 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 *RAS* mutant 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 Tarlatamab
Tarlatamab is an investigational, targeted immunotherapy engineered by Amgen researchers that brings a patient's own T cells in close proximity to SCLC cells by binding both CD3 on T cells and DLL3 on SCLC cells. This results in the formation of an immunological synapse with lysis of the cancer cell.[14,15] DLL3 represents an exciting therapeutic target for patients with SCLC, as approximately 85% to 94% of patients have expression of DLL3 on the cell surface of SCLC cells, with minimal expression in normal cells.[16,17,18]

Amgen is currently investigating tarlatamab in multiple trials, including DeLLphi-304, a Phase 3 study comparing tarlatamab versus standard of care chemotherapy in second-line treatment of SCLC that is enrolling patients. Amgen has plans to initiate two additional Phase 3 studies of tarlatamab in earlier settings of SCLC.

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.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2023, Amgen was named one of "America's Greatest Workplaces" by Newsweek, one of "America's Climate Leaders" by USA Today and one of the "World's Best Companies" by TIME.

For more information, visit Amgen.com and follow us on X (formerly known as Twitter), 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), the Teneobio, Inc. acquisition, the ChemoCentryx, Inc. acquisition, or the Horizon Therapeutics plc acquisition (including the prospective performance and outlook of Horizon's business,

performance and opportunities and any potential strategic benefits, synergies or opportunities expected as a result of such 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 on our 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 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 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. There can be no guarantee that we 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. We may not be able to successfully integrate Horizon, and such acquisition or integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach of our information technology systems 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. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. 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.

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