AMGEN PRESENTS NEW DATA FOR FIRST-IN-CLASS IMDELLTRA™ (TARLATAMAB-DLLE) IN SMALL CELL LUNG CANCER AT WCLC 2024

September 9, 2024

DeLLphi-303 Study Results Show Potential for IMDELLTRA in Combination with a PD-L1 Inhibitor as First-Line Maintenance Therapy in ES-SCLC

DeLLphi-301 Long-Term Follow-up Data Demonstrate Sustained Safety and Efficacy for IMDELLTRA

THOUSAND OAKS, Calif., Sept. 9, 2024 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the presentation of new data showcasing IMDELLTRA™ (tarlatamab-dlle), a first-in-class delta-like ligand 3 (DLL3)-targeting Bispecific T-cell Engager (BiTE®) molecule, at the 2024 World Conference on Lung Cancer (WCLC) in San Diego.

IMDELLTRA will be featured in two oral presentations at the "DLL3 Targeting BiTE Therapies in SCLC" session, taking place today at 2:00 p.m. PDT. New data from the global Phase 1b DeLLphi-303 study of IMDELLTRA combined with PD-L1 inhibitors in first-line maintenance extensive-stage small cell lung cancer (ES-SCLC) will be presented as a late-breaking abstract (#LBA OA10.04). Additionally, long-term results from the Phase 2 DeLLphi-301 study in previously treated ES-SCLC will be highlighted as an oral presentation (#OA10.03).

"Earlier this year, the FDA approved IMDELLTRA for patients with extensive-stage small cell lung cancer who progressed on or after platinum-based chemotherapy. Today, we are thrilled to share results showing long-term sustained benefit in this setting as well as initial evidence supporting a combination approach in front-line maintenance therapy," said Jay Bradner, M.D., executive vice president, Research and Development, and chief scientific officer at Amgen. "These data support our goal to deliver an effective targeted immunotherapy to more patients living with this aggressive cancer."

DeLLphi-303 Phase 1b Study Data in First-Line Maintenance Therapy
IMDELLTRA combined with a PD-L1 inhibitor as first-line maintenance therapy in ES-SCLC demonstrated a manageable safety profile with sustained disease control and positive survival outcomes. Key findings include:

- IMDELLTRA plus a PD-L1 inhibitor: demonstrated a positive benefit: risk profile with no new or unexpected safety findings
- IMDELLTRA plus durvalumab: disease control rate (DCR) of 62.5% (95% CI: 45.8-77.3) and median duration of disease control (DoDC) that was Not Estimable (95% CI: 3.9, NE)
- IMDELLTRA plus atezolizumab: DCR of 62.5% (95% CI: 47.4-76.0) and median DoDC of 7.2 months (95% CI: 5.6, NE)
- Following a median time of 3.5 months from first-line chemoimmunotherapy to first-line maintenance:
    - IMDELLTRA plus durvalumab showed a 9-month overall survival (OS) of 91.8% (95% CI: 76.6-97.3) and median progression-free survival (mPFS) of 5.3 months (95% CI: 3.5-NE)
    - IMDELLTRA plus atezolizumab showed a 9-month OS of 86.7% (95% CI: 70.3-94.4) and mPFS of 5.6 months (95% CI: 3.5-8.5)

"Tarlatamab has been a major breakthrough for patients with extensive-stage small cell lung cancer, who have had limited options for the past 30 years, and these data are impressive as a potential first-line maintenance treatment as well," said Sally Lau, M.D., oncologist and assistant professor of medicine, Perlmutter Cancer Center, NYU Grossman School of Medicine. "In particular, tarlatamab in combination with a PD-L1 inhibitor showed exciting safety and efficacy, which strongly supports continued evaluation in the ongoing Phase 3 DeLLphi-305 trial."

In patients receiving IMDELLTRA plus durvalumab, treatment-related adverse events (TRAEs) resulted in dose interruptions in 15% of cases and discontinuation in 8% of patients. In the IMDELLTRA plus atezolizumab treatment arm, TRAEs led to dose interruptions in 17% of cases and discontinuation of IMDELLTRA in 4% of patients. Cytokine release syndrome (CRS) was mostly grade 1-2, occurring primarily in cycle 1 and generally manageable with supportive care. Immune effector cell-associated neurotoxicity syndrome (ICANS) was infrequent overall, with a lower incidence and severity observed in the IMDELLTRA plus durvalumab treatment arm compared to IMDELLTRA plus atezolizumab treatment arm.

DeLLphi-301 Phase 2 Extended Follow-up Data in ES-SCLC
Extended follow-up data from the DeLLphi-301 Phase 2 study demonstrated sustained anticancer activity and a manageable safety profile with IMDELLTRA in patients with ES-SCLC previously treated with platinum-based chemotherapy.

Among 100 patients treated with IMDELLTRA 10 mg biweekly, the objective response rate (ORR) was 40%, with nearly half of the responders maintaining their response at data cutoff. Stable disease was observed in 30% of the patients, and the median duration of disease control was 6.9 months (95% CI, 5.4-8.6). Median OS for this group was 15.2 months and was similar regardless of progression-free interval (<90 days or 90+ days) after first-line platinum-based chemotherapy. IMDELLTRA demonstrated long-term tolerability with no new safety concerns identified. These findings support the continued use of IMDELLTRA in this patient population, underscoring its clinical significance.

About DeLLphi-303 Study
Preclinical studies indicated that IMDELLTRA upregulated PD-L1 expression and demonstrated increased cytotoxic activity when combined with a PD-L1 inhibitor.[1,2]

The DeLLphi-303 study is a Phase 1b, multicenter, open-label study evaluating the safety and efficacy of first-line IMDELLTRA in combination with standard-of-care chemoimmunotherapy, followed by IMDELLTRA plus PD-L1 inhibitor, in patients with ES-SCLC.

DeLLphi-303 will also evaluate IMDELLTRA in combination with a PD-L1 inhibitor as first-line maintenance only following standard-of-care

chemoimmunotherapy. This part of the study includes 88 patients assigned to receive either IMDELLTRA 10 mg administered intravenously (IV) every two weeks plus atezolizumab 1680 mg IV every four weeks (n=48), or IMDELLTRA 10 mg IV every two weeks plus durvalumab 1500 mg IV every four weeks (n=40). The study protocol allowed for switching of PD-L1 inhibitor for the maintenance treatment, from that received by the patient during initial first-line treatment with platinum-based chemotherapy.

The primary endpoint in DeLLphi-303 is safety and tolerability of IMDELLTRA in combination with a PD-L1 inhibitor, with or without chemotherapy. For the investigation of IMDELLTRA in front-line with chemoimmunotherapy followed by maintenance with a PD-L1 inhibitor, the secondary endpoints include ORR, duration of response (DoR), DCR, PFS and OS. For the investigation of IMDELLTRA in first-line maintenance following front-line standard-of-care chemoimmunotherapy, the secondary endpoints include DCR, PFS, and OS, beginning from the start of first-line maintenance.

About DeLLphi-301 Study
The U.S. Food and Drug Administration accelerated approval of IMDELLTRA is based on results from the Phase 2 DeLLphi-301 clinical trial, in which IMDELLTRA at 10 mg or 100 mg dosed once every 2 weeks was evaluated in patients with SCLC who were refractory to or relapsed after one platinum-based regimen, with or without a checkpoint inhibitor, and at least one other line of therapy. The primary efficacy endpoint was ORR per RECIST 1.1 by blinded independent central review. In part 2 of the study, additional patients were enrolled at the 10 mg dose until 100 patients were reached, and Part 3 was a safety sub-study that evaluated a shortened monitoring period at a medical facility following administration of the first two doses of IMDELLTRA. Across all parts, patients received an initial 1 mg step up dose on day 1, followed by the 10 mg or 100 mg target doses on days 8 and 15 of cycle 1, and then every two weeks in 28-day cycles until disease progression.

About IMDELLTRA™ (tarlatamab-dlle)
IMDELLTRA received accelerated approval from the U.S. Food and Drug Administration on May 16, 2024. IMDELLTRA is a first-in-class immunotherapy engineered by Amgen researchers that binds to both DLL3 on cancer cells and CD3 on T cells, creating a cytolytic synapse between T cells and cancer cells. The activated T cells then mediate lysis of DLL3-expressing SCLC cells.[1,3] DLL3 is a protein that is expressed on the surface of SCLC cells in ~85-96% of patients with SCLC, but is minimally expressed on healthy cells, making it an exciting target.[4,5]

IMDELLTRA™ (tarlatamab-dlle) U.S. Indication
IMDELLTRA™ (tarlatamab-dlle) is indicated for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.

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

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving IMDELLTRA™. Initiate treatment with IMDELLTRA™ using the step-up dosing schedule to reduce the incidence and severity of CRS. Withhold IMDELLTRA™ until CRS resolves or permanently discontinue based on severity.**
- **Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including serious or life-threatening reactions, can occur in patients receiving IMDELLTRA™. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment and treat promptly. Withhold IMDELLTRA™ until ICANS resolves or permanently discontinue based on severity.**

WARNINGS AND PRECAUTIONS

- **Cytokine Release Syndrome (CRS):** IMDELLTRA™ can cause CRS including serious or life-threatening reactions. In the pooled safety population, CRS occurred in 55% of patients who received IMDELLTRA™, including 34% Grade 1, 19% Grade 2, 1.1% Grade 3 and 0.5% Grade 4. Recurrent CRS occurred in 24% of patients, including 18% Grade 1 and 6% Grade 2.

  Most events (43%) of CRS occurred after the first dose, with 29% of patients experiencing any grade CRS after the second dose and 9% of patients experiencing CRS following the third dose or later. Following the Day 1, Day 8, and Day 15 infusions, 16%, 4.3% and 2.1% of patients experienced ≥ Grade 2 CRS, respectively. The median time to onset of all grade CRS from most recent dose of IMDELLTRA™ was 13.5 hours (range 1 to 268 hours). The median time to onset of ≥ Grade 2 CRS from most recent dose of IMDELLTRA™ was 14.6 hours (range: 2 to 566 hours).

  Clinical signs and symptoms of CRS included pyrexia, hypotension, fatigue, tachycardia, headache, hypoxia, nausea, and vomiting. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

  Administer IMDELLTRA™ following the recommended step-up dosing and administer concomitant medications before and after Cycle 1 IMDELLTRA™ infusions as described in Table 3 of the Prescribing Information (PI) to reduce the risk of CRS. Administer IMDELLTRA™ in an appropriate health care facility equipped to monitor and manage CRS. Ensure patients are well hydrated prior to administration of IMDELLTRA™.

Closely monitor patients for signs and symptoms of CRS during treatment with IMDELLTRA™. At the first sign of CRS, immediately discontinue IMDELLTRA™ infusion, evaluate the patient for hospitalization and institute supportive care based on severity. Withhold or permanently discontinue IMDELLTRA™ based on severity. Counsel patients to seek medical attention should signs or symptoms of CRS occur.

- **Neurologic Toxicity, Including ICANS**: IMDELLTRA™ can cause serious or life-threatening neurologic toxicity, including ICANS. In the pooled safety population, neurologic toxicity, including ICANS, occurred in 47% of patients who received IMDELLTRA™, including 10% Grade 3. The most frequent neurologic toxicities were headache (14%), peripheral neuropathy (7%), dizziness (7%), insomnia (6%), muscular weakness (3.7%), delirium (2.1%), syncope (1.6%), and neurotoxicity (1.1%).

  ICANS occurred in 9% of IMDELLTRA™-treated patients. Recurrent ICANS occurred in 1.6% of patients. Most patients experienced ICANS following Cycle 2 Day 1 (24%). Following Day 1, Day 8, and Day 15 infusions, 0.5%, 0.5% and 3.7% of patients experienced ≥ Grade 2 ICANS, respectively. The median time to onset of ICANS from the first dose of IMDELLTRA™ was 29.5 days (range: 1 to 154 days). ICANS can occur several weeks following administration of IMDELLTRA™. The median time to resolution of ICANS was 33 days (range 1 to 93 days).

  The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

  Patients receiving IMDELLTRA™ are at risk of neurologic adverse reactions and ICANS resulting in depressed level of consciousness. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, in the event of any neurologic symptoms until they resolve.

  Closely monitor patients for signs and symptoms of neurologic toxicity and ICANS during treatment. At the first sign of ICANS, immediately evaluate the patient and provide supportive therapy based on severity. Withhold IMDELLTRA™ or permanently discontinue based on severity.

- **Cytopenias:** IMDELLTRA™ can cause cytopenias including neutropenia, thrombocytopenia, and anemia. In the pooled safety population, decreased neutrophils occurred in 12% including 6% Grade 3 or 4 of IMDELLTRA™-treated patients. The median time to onset for Grade 3 or 4 neutropenia was 29.5 days (range: 2 to 213). Decreased platelets occurred in 33% including 3.2% Grade 3 or 4. The median time to onset for Grade 3 or 4 decreased platelets was 50 days (range: 3 to 420). Decreased hemoglobin occurred in 58% including 5% Grade 3 or 4. Febrile neutropenia occurred in 0.5% of patients treated with IMDELLTRA™.

  Monitor patients for signs and symptoms of cytopenias. Perform complete blood counts prior to treatment with IMDELLTRA™, before each dose, and as clinically indicated. Based on the severity of cytopenias, temporarily withhold, or permanently discontinue IMDELLTRA™.

- **Infections:** IMDELLTRA™ can cause serious infections, including life-threatening and fatal infections. In the pooled safety population, infections, including opportunistic infections, occurred in 41% of patients who received IMDELLTRA™. Grade 3 or 4 infections occurred in 13% of patients. The most frequent infections were COVID-19 (9%, majority during the COVID-19 pandemic), urinary tract infection (10%), pneumonia (9%), respiratory tract infection (3.2%), and candida infection (3.2%).

  Monitor patients for signs and symptoms of infection prior to and during treatment with IMDELLTRA™ and treat as clinically indicated. Withhold or permanently discontinue IMDELLTRA™ based on severity.

- **Hepatotoxicity:** IMDELLTRA™ can cause hepatotoxicity. In the pooled safety population, elevated ALT occurred in 42%, with Grade 3 or 4 ALT elevation occurring in 2.1%. Elevated AST occurred in 44% of patients, with Grade 3 or 4 AST elevation occurring in 3.2%. Elevated bilirubin occurred in 15% of patients; Grade 3 or 4 total bilirubin elevations occurred in 1.6% of patients. Liver enzyme elevation can occur with or without concurrent CRS. Monitor liver enzymes and bilirubin prior to treatment with IMDELLTRA™, before each dose, and as clinically indicated. Withhold IMDELLTRA™ or permanently discontinue based on severity.

- **Hypersensitivity:** IMDELLTRA™ can cause severe hypersensitivity reactions. Clinical signs and symptoms of

hypersensitivity may include, but are not limited to, rash and bronchospasm. Monitor patients for signs and symptoms of hypersensitivity during treatment with IMDELLTRA™ and manage as clinically indicated. Withhold or consider permanent discontinuation of IMDELLTRA™ based on severity.

- **Embryo-Fetal Toxicity:** Based on its mechanism of action, IMDELLTRA™ may cause fetal harm when administered to a pregnant woman. Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IMDELLTRA™ and for 2 months after the last dose.

ADVERSE REACTIONS

- The most common (> 20%) adverse reactions were CRS (55%), fatigue (51%), pyrexia (36%), dysgeusia (36%), decreased appetite (34%), musculoskeletal pain (30%), constipation (30%), anemia (27%) and nausea (22%). The most common (≥ 2%) Grade 3 or 4 laboratory abnormalities were decreased lymphocytes (57%), decreased sodium (16%), increased uric acid (10%), decreased total neutrophils (6%), decreased hemoglobin (5%), increased activated partial thromboplastin time (5%), decreased potassium (5%), increased aspartate aminotransferase (3.2%), decreased white blood cells (3.8%), decreased platelets (3.2%), and increased alanine aminotransferase (2.1%).
- Serious adverse reactions occurred in 58% of patients. Serious adverse reactions in > 3% of patients included CRS (24%), pneumonia (6%), pyrexia (3.7%), and hyponatremia (3.6%). Fatal adverse reactions occurred in 2.7% of patients including pneumonia (0.5%), aspiration (0.5%), pulmonary embolism (0.5%), respiratory acidosis (0.5%), and respiratory failure (0.5%).

DOSAGE AND ADMINISTRATION: Important Dosing Information

- Administer IMDELLTRA™ as an intravenous infusion over one hour.
- Administer IMDELLTRA™ according to the step-up dosing schedule in the IMDELLTRA™ PI (Table 1) to reduce the incidence and severity of CRS.
- For Cycle 1, administer recommended concomitant medications before and after Cycle 1 IMDELLTRA™ infusions to reduce the risk of CRS reactions as described in the PI (Table 3).
- IMDELLTRA™ should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity including ICANS.
- Due to the risk of CRS and neurologic toxicity, including ICANS, monitor patients from the start of the IMDELLTRA™ infusion for 22 to 24 hours on Cycle 1 Day 1 and Cycle 1 Day 8 in an appropriate healthcare setting.
- Recommend that patients remain within 1 hour of an appropriate healthcare setting for a total of 48 hours from start of the infusion with IMDELLTRA™ following Cycle 1 Day 1 and Cycle 1 Day 8 doses, accompanied by a caregiver.
- Prior to administration of IMDELLTRA™ evaluate complete blood count, liver enzymes, and bilirubin before each dose, and as clinically indicated.
- Ensure patients are well hydrated prior to administration of IMDELLTRA™.

Please see IMDELLTRA™full Prescribing Information, including BOXED WARNINGS

About Small Cell Lung Cancer
SCLC is one of the most aggressive and devastating solid tumor malignancies, with a median survival of approximately 12 months following initial therapy and a 3% five-year relative survival rate for ES-SCLC.[6,7,8] Current second-line treatments impart a short duration of response (median DoR: 3.3–5.3 months) and limited survival (median OS: 5.8-9.3 months), while current third-line treatments for SCLC, which consist primarily of chemotherapy, yield a short median DoR of 2.6 months and a median OS of 4.4-5.3 months.[9,10,11,12,13] SCLC comprises ~15% of the 2.4 million plus patients diagnosed with lung cancer worldwide each year.[14,15,16] Despite initial high response rates to first-line platinum-based chemotherapy, most patients quickly relapse within months and require subsequent treatment options.[14]

About IMDELLTRA (tarlatamab-dlle) Clinical Trials
Amgen's robust IMDELLTRA development program includes the DeLLphi clinical trials, which evaluate IMDELLTRA as both a monotherapy and in combination regimens in earlier lines of SCLC, and DeLLpro clinical trials, which evaluate the efficacy and safety of tarlatamab in neuroendocrine prostate cancer.

In the Phase 1 DeLLphi-300 study, IMDELLTRA showed responses in 23.4% of patients with encouraging durability in heavily pre-treated patients with SCLC.[17] In the Phase 2 DeLLphi-301 study, IMDELLTRA administered as 10 mg dose every two weeks demonstrated an ORR of 40% in patients with advanced SCLC who had failed two or more prior lines of treatment. In the DeLLphi-301 Phase 2 trial, the most frequent treatment-related adverse events seen with 10 mg Q2W dosing regimen were CRS (51%), pyrexia (32%), and decreased appetite (23%). CRS events were predominantly grade 1 or 2 and occurred most often after the first or second dose.[2] Treatment discontinuation for adverse events occurred in 4-7% of patients in the two trials.[4,17]

Tarlatamab is being investigated in multiple studies including DeLLphi-303, a Phase 1b study investigating tarlatamab in combination with standard-of-care therapies in first-line ES-SCLC; DeLLphi-304, a randomized Phase 3 trial comparing tarlatamab monotherapy with standard-of-care chemotherapy in second-line treatment of SCLC; DeLLphi-305, a randomized Phase 3 trial comparing tarlatamab in combination with durvalumab versus durvalumab alone as first-line maintenance treatment in ES-SCLC; DeLLphi-306, a randomized placebo-controlled Phase 3 trial of tarlatamab

following concurrent chemoradiotherapy in limited-stage SCLC; and DeLLpro-300, a Phase 1b study of tarlatamab in de novo or treatment-emergent neuroendocrine prostate cancer.[18]

For more information, please visit https://tarlatamabclinicaltrials.com/.

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), our 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 our 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 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 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. 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 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.

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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