FDA APPROVES IMDELLTRA™ (TARLATAMAB-DLLE), THE FIRST AND ONLY T-CELL ENGAGER THERAPY FOR THE TREATMENT OF EXTENSIVE-STAGE SMALL CELL LUNG CANCER

May 16, 2024

Breakthrough DLL3-Targeting Therapy Regimen for a Major Solid Tumor

IMDELLTRA Demonstrated Impressive 40% Objective Response Rate, 9.7 Month Median Duration of Response and 14.3 Month Median Overall Survival in Pivotal DeLLphi-301 Study

Amgen to Host Webcast Investor Call on May 20, 2024 at 1:00 p.m. PT

THOUSAND OAKS, Calif., May 16, 2024 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved IMDELLTRA™ (tarlatamab-dlle) for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy. IMDELLTRA has received accelerated approval based on the encouraging response rate and duration of response (DoR) observed in clinical studies. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Experience the full interactive Multichannel News Release here: https://www.multivu.com/players/English/9246451-fda-approves-imdelltra-tarlatamab-dlle-the-first-and-only-t-cell-engager-therapy-for-the-treatment-of-extensive-stage-small-cell-lung-cancer/

"The FDA's approval of IMDELLTRA marks a pivotal moment for patients battling ES-SCLC. This DLL3-targeting therapy in ES-SCLC comprises a transformative option demonstrating long-lasting responses in pretreated patients," said Jay Bradner, M.D., executive vice president, Research and Development, and chief scientific officer at Amgen. "This approval further demonstrates our commitment to addressing aggressive cancers through our second FDA-approved Bispecific T-cell Engager (BiTE®) molecule. IMDELLTRA offers these patients who are in urgent need of new innovative therapies hope, and we're proud to deliver this long-awaited effective treatment to them."

"Lung cancer is a complex and devastating disease, and less than 3% of patients with ES-SCLC live longer than five years," said David P. Carbone, M.D., Ph.D., professor of internal medicine and director of the James Thoracic Oncology Center at the Ohio State University Medical Center.[1] "In the DeLLphi-301 trial, the median overall survival was 14.3 months, with 40% of patients responding to treatment with tarlatamab. These responses were remarkably durable, representing a major advancement in the SCLC treatment paradigm."

IMDELLTRA is the first and only DLL3-targeting Bispecific T-cell Engager therapy that activates the patient's own T cells to attack DLL3-expressing tumor cells.[2]

"After decades of minimal advancements in the SCLC treatment landscape, there is now an effective and innovative treatment option available," said Laurie Fenton Ambrose, co-founder, president, and CEO of GO2 for Lung Cancer. "Today's FDA approval marks a significant milestone for the SCLC community as the availability of a targeted bispecific therapy brings forward new possibilities to those living with this aggressive disease."

The FDA accelerated approval of IMDELLTRA is based on results from the Phase 2 DeLLphi-301 clinical trial that evaluated IMDELLTRA in patients with SCLC who had failed two or more prior lines of treatment, and who had received the 10 mg every two weeks dosing (Q2W) regimen. Results from the study found that IMDELLTRA at the 10 mg Q2W dose (N=99) demonstrated a robust objective response rate (ORR) of 40% (95% Confidence Interval [CI]: 31, 51) and median DoR of 9.7 months (CI: 2.7, 20.7+). The median overall survival (mOS) was 14.3 months, with final and complete survival data yet to mature.[3]

The IMDELLTRA label includes a Boxed Warning for cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), in addition to warnings and precautions for cytopenias, infections, hepatotoxicity, hypersensitivity, and embryo-fetal toxicity. The most common (> 20%) adverse reactions reported among patients were CRS (55%), fatigue (51%), pyrexia (36%), dysgeusia (36%), decreased appetite (34%), musculoskeletal pain (30%), constipation (30%), anemia (27%), and nausea (22%). Permanent discontinuations due to treatment-emergent adverse events (TEAEs) were infrequent (7%). CRS was largely confined to the first and second dose, predominantly grade 1 or 2, and was generally managed with supportive care. Details of the Important Safety Information are included below.

Amgen's Commitment to Patient Support
Amgen is committed to supporting patients with ES-SCLC and to helping ensure appropriate patients with access to IMDELLTRA. Patients, caregivers, and physicians who need support, tools, or resources can contact Amgen® SupportPlus. Amgen also provides patient assistance for its medicines marketed in the U.S. in a variety of ways, including for uninsured or under-insured patients through the Amgen Safety Net Foundation, a nonprofit patient assistance program sponsored by Amgen that helps qualifying patients access Amgen medicines at no cost.

Amgen to Webcast Investor Call on IMDELLTRA FDA Approval
Amgen will host a webcast call for the investment community on Monday, May 20, 2024 at 1:00 p.m. PT (4:00 p.m. ET). Jay Bradner, M.D., executive vice president, Research and Development, and chief scientific officer at Amgen, Murdo Gordon, executive vice president of Global Commercial Operations, and other members of the Amgen team will participate.

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

About IMDELLTRA™ (tarlatamab-dlle)
IIMDELLTRA is a first-in-class immunotherapy engineered by Amgen researchers that binds to both DLL3 on tumor cells and CD3 on T cells, activating T cells to kill DLL3-expressing SCLC cells. This results in the formation of a cytolytic synapse with lysis of the cancer cell.[2,4] 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.[3,5]

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).

IMDELLTRA™ (tarlatamab-dlle) 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)
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.[1,6,7] 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.[8-12] SCLC comprises ~15% of the 2.4 million plus patients diagnosed with lung cancer worldwide each year.[13-15] Despite initial high response rates to first-line platinum-based chemotherapy, most patients quickly relapse within months and require subsequent treatment options.[13]

About Tarlatamab Clinical Trials
Amgen's robust tarlatamab development program includes the DeLLphi clinical trials, which evaluate tarlatamab 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, tarlatamab showed responses in 23.4% of patients with encouraging durability in heavily pre-treated patients with SCLC.[16] In the Phase 2 DeLLphi-301 study, tarlatamab 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.[3,16]

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.[17]

For more information, please visit www.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.

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
Elissa Snook, 609-251-1407 (media)
Justin Claeys, 805-313-9775 (investors)

References

1. American Cancer Society. Lung Cancer Survival Rates. www.cancer.org/cancer/types/lung-cancer/detection-diagnosis-staging/survival-rates.html. Accessed on March 15, 2024.
2. Giffin MJ, Cooke K, Lobenhofer EK, et al. AMG 757, a Half-Life Extended, DLL3-Targeted Bispecific T-Cell Engager, Shows High Potency and Sensitivity in Preclinical Models of Small-Cell Lung Cancer. *Clin Cancer Res*. 2021;27:1526-1537.
3. Ahn MJ, Cho BC, Felip E, et al. Tarlatamab for Patients with Previously Treated Small-Cell Lung Cancer. *N Engl J Med*. 2023;389:2063-2075.
4. Baeuerle PA, Kufer P, Bargou R. BiTE: Teaching antibodies to engage T-cells for cancer therapy. *Curr Opin Mol Ther*.

2009;11:22-30.
5. Rojo F, Corassa M, Mavroudis D, et al. International real-world study of DLL3 expression in patients with small cell lung cancer. *Lung Cancer.* 2020;147:237-243.
6. Paz-Ares L, Chen Y, Reinmuth N, et al. Durvalumab, with or without tremelimumab, plus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer: 3-year overall survival update from CASPIAN. *ESMO Open*. 2022;7:100408.
7. Liu SV, Reck M, Mansfield AS, et al. Updated Overall Survival and PD-L1 Subgroup Analysis of Patients With Extensive-Stage Small-Cell Lung Cancer Treated With Atezolizumab, Carboplatin, and Etoposide (IMpower133). *J Clin Oncol*. 2021;39:619-630.
8. Trigo J, Subbiah V, Besse B, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncol*. 2020;21(5):645-654.
9. Von Pawel J, Schiller JH, Shepherd FA, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol*. 1999;17(2):658-67.
10. Von Pawel J, Jotte R, Spigel DR, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. *J Clin Oncol*. 2014;32(35):4012-9.
11. Coutinho AD, Shah M, Lunacsek OE, et al. Real-world treatment patterns and outcomes of patients with small cell lung cancer progression after 2 lines of therapy. *Lung Cancer*. 2019;127:53-58.
12. Borghaei H, Pundole X, Anderson E, et al. Treatment patterns and outcomes in recent US clinical practice for SCLC patients after two prior lines of therapy. Presentation at World Conference on Lung Cancer 2023. September 9-12, 2023; Singapore, SGP. Poster #EP13.07-03.
13. Oronsky B, Abrouk N, Caroen S, et al. A 2022 Update on Extensive Stage Small-Cell Lung Cancer (SCLC). *J Cancer*. 2022;13:2945-2953.
14. World Health Organization. Lung. 2020. https://gco.iarc.who.int/media/globocan/factsheets/cancers/15-trachea-bronchus-and-lung-fact-sheet.pdf. Accessed on March 15, 2024.
15. Sabari JK, Lok BH, Laird JH, et al. Unravelling the biology of SCLC: implications for therapy. *Nat Rev Clin Oncol*. 2017;14:549-561.
16. Paz-Ares L, Champiat S, Lai WV, et al. Tarlatamab, a First-in-Class DLL3-Targeted Bispecific T-Cell Engager, in Recurrent Small-Cell Lung Cancer: An Open-Label, Phase I Study. *J Clin Oncol*. 2023;41:2893-2903.
17. Clinical Trials. Tarlatamab Clinical Trial Listings. www.clinicaltrials.gov. Accessed March 15, 2024.

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