FDA GRANTS FULL APPROVAL TO AMGEN'S IMDELLTRA® IN EXTENSIVE STAGE SMALL CELL LUNG CANCER

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Global Confirmatory Phase 3 DeLLphi-304 Trial Showed IMDELLTRA Reduced Risk of Death by 40% Compared to Chemotherapy

Underscores IMDELLTRA as a Recognized Standard of Care Treatment for Patients With Extensive Stage Small Cell Lung Cancer That Has Progressed

THOUSAND OAKS, Calif., Nov. 19, 2025 /PRNewswire/ -- Amgen (NASDAQ: AMGN) announced today that the U.S. Food and Drug Administration (FDA) has granted full approval to 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. The decision to convert IMDELLTRA's prior accelerated approval to a full approval is based on data from the global Phase 3 DeLLphi-304 study. Additionally, the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) were recently updated to include tarlatamab as the only Category 1 preferred treatment option for adult patients with ES-SCLC with disease progression on or after platinum-based chemotherapy.[1]*

The global Phase 3 DeLLphi-304 study met its primary endpoint, demonstrating that IMDELLTRA reduced the risk of death by 40% and significantly extended median overall survival (OS) by more than five months compared to standard of care (SOC) chemotherapy as a treatment for patients with ES-SCLC who progressed on or after one line of platinum-based chemotherapy (median OS: 13.6 vs. 8.3 months; hazard ratio (HR), 0.60; 95% confidence interval (CI): 0.47, 0.77; P < 0.001).[2]

"The FDA's decision reinforces IMDELLTRA as a recognized standard of care for people living with extensive stage small cell lung cancer whose disease progressed on or after frontline therapy," said Jay Bradner, M.D., executive vice president, Research and Development, at Amgen. "We are committed to delivering transformative medicines for patients facing challenging cancers, and we are currently focused on rapidly developing IMDELLTRA in earlier stages of disease and earlier lines of therapy for small cell lung cancer patients."

"For far too long, people living with small cell lung cancer had few options once their first treatment stopped working," said Laurie Fenton Ambrose, co-founder, president, and CEO, GO2 for Lung Cancer. "Today's full approval is an important step forward, reinforcing long-awaited progress for patients facing this devastating disease."

The safety profile for IMDELLTRA in DeLLphi-304 was consistent with its known profile, with fewer Grade 3 or greater adverse events in the IMDELLTRA arm than in the chemotherapy arm (54% vs 80%). The most common Grade 3 or greater treatment-related adverse events (TRAEs) were neutropenia (4%) and lymphopenia (4%) with IMDELLTRA and anemia (28%) and neutropenia (22%) with SOC chemotherapy. Cytokine release syndrome (CRS) with IMDELLTRA primarily occurred after the first two doses and was primarily low grade (42% Grade 1; 13% Grade 2; 1% Grade 3). No Grade 4 or Grade 5 CRS events were reported.[2]

"Due to its distinctive biology and aggressive nature, small cell lung cancer has long been particularly challenging to treat, with limited progress compared to many other cancers. After years of research efforts, DeLLphi-304 was the first global Phase 3 trial to demonstrate a significant survival benefit over chemotherapy in its setting, leading to NCCN Guidelines® Category 1 status for tarlatamab and further demonstrating the validity of this treatment approach in small cell lung cancer," said Charles M. Rudin, M.D., Ph.D., deputy director, Memorial Sloan Kettering Cancer Center, and principal investigator.* "Importantly, data from DeLLphi-304 reflected in today's approval also equip physicians with a greater understanding of managing treatment with bispecific T-cell engager therapy."

Amgen's robust IMDELLTRA development program includes the DeLLphi clinical trials, which evaluate IMDELLTRA as a monotherapy and as part of combination regimens, including in both earlier stages of SCLC and earlier lines of treatment.

About the Phase 3 DeLLphi-304 Study

DeLLphi-304 is a global Phase 3, randomized, controlled, open-label clinical trial evaluating the efficacy and safety of IMDELLTRA as a treatment for patients living with SCLC who progressed on or after a single line of platinum-based chemotherapy.[3] Five hundred and nine patients were randomized to receive either IMDELLTRA or local SOC chemotherapy (topotecan in all countries except Japan; lurbinectedin in the U.S., Canada, Australia, Singapore, Korea; and amrubicin in Japan).[3,4] The primary outcome measure of the trial is OS.[3] Key secondary outcome measures include progression-free survival (PFS) and patient-reported outcomes (PROs) including disease-related symptoms, physical function, and quality of life.[3] Results from DeLLphi-304 were reviewed as a late-breaking presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in *The New England Journal of Medicine.*[2,5]

About Tarlatamab Clinical Trials

Tarlatamab is being investigated in multiple studies including DeLLphi-303, a Phase 1b study investigating tarlatamab in combination with SOC therapies in first-line ES-SCLC; DeLLphi-304, a randomized Phase 3 study comparing tarlatamab monotherapy with SOC chemotherapy in second-line treatment of SCLC; DeLLphi-305, a randomized Phase 3 study comparing tarlatamab in combination with durvalumab vs. durvalumab alone as first-line maintenance treatment in ES-SCLC; DeLLphi-306, a randomized placebo-controlled Phase 3 study of tarlatamab following concurrent chemoradiotherapy in limited-stage SCLC; DeLLphi-308, a Phase 1b study evaluating subcutaneous tarlatamab in second-line or later ES-SCLC; DeLLphi-309, a Phase 2 study evaluating alternative intravenous dosing regimens with tarlatamab in second-line ES-SCLC; DeLLphi-310, a Phase 1b study of tarlatamab in combination with YL201 with or without anti-programmed death ligand 1 (PD-L1) in patients with ES-SCLC; DeLLphi-311, a Phase 1b study of IMDELLTRA in combination with etakafusp alfa (AB248), a novel CD8+ T-cell selective interleukin-2 (IL-2), in patients with ES-SCLC; and DeLLphi-312, a Phase 3 study evaluating tarlatamab as an induction and maintenance therapy in first-line treatment of ES-SCLC in combination with carboplatin, etoposide and durvalumab.[6]

For more information, please visit www.tarlatamabclinicaltrials.com.

About Small Cell Lung Cancer (SCLC)
SCLC is one of the most aggressive and devastating forms of solid tumor cancers. In the United States, the five-year relative survival rate for SCLC is 5-10% across all stages combined.[7] Each year, SCLC accounts for approximately 13-15% of the more than 2.4 million cases of lung cancer diagnosed worldwide, including around 227,000 cases in the United States.[8-10] Despite initial high response rates to first-line platinum-based chemotherapy, most patients quickly relapse within months and require subsequent treatment options.[9]

About IMDELLTRA® (tarlatamab-dlle)
IMDELLTRA is a first-in-class targeted immunotherapy engineered by Amgen researchers to bind to both DLL3 on tumor cells and CD3 on T cells, thereby activating T cells to kill DLL3-expressing SCLC cells. This results in the formation of a cytolytic synapse with lysis of the cancer cell.[11,12] 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.[13,14]

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.

IMPORTANT SAFETY INFORMATION

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

- **Cytokine release syndrome (CRS), including life-threatening or fatal 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 and immune effector cell-associated neurotoxicity syndrome (ICANS), including life-threatening or fatal 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 life-threatening or fatal reactions. In the pooled safety population, CRS occurred in 57% (268/473) of patients who received IMDELLTRA®, including 39% Grade 1, 15% Grade 2, 1.7% Grade 3 and 0.2% Grade 4. Recurrent CRS occurred in 24% of IMDELLTRA®-treated patients including 20% Grade 1 and 3.4% Grade 2; one patient experienced recurrent Grade 3.

  Among the 268 patients who experienced CRS, 73% had CRS after the first dose, 60% had CRS after the second dose, and 15% had CRS following the third or later dose. Following the Cycle 1 Day 1, Day 8, Day 15 infusions, 24%, 8%, and 1% of patients experienced Grade ≥ 2 CRS, respectively. From Cycle 2 onwards, 1.5% of patients experienced Grade ≥ 2 CRS. Of the patients who experienced CRS, 31% received steroids and 10% required tocilizumab. The median time to onset of all grade CRS from most recent dose of IMDELLTRA® was 16 hours (range: start of infusion to 15 days). The median time to onset of Grade ≥ 2 CRS from most recent dose of IMDELLTRA® was 15 hours (range: start of infusion to 15 days).

  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 Day 1 and Cycle 1 Day 8 IMDELLTRA® infusions as described in Table 3 of the Prescribing Information (PI) to reduce the risk of CRS. Administer IMDELLTRA® in an appropriate healthcare 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 and caregivers to seek medical attention should signs or symptoms of CRS occur.

- **Neurologic Toxicity, Including ICANS**: IMDELLTRA® can cause life-threatening or fatal neurologic toxicity, including ICANS. In the pooled safety population, neurologic toxicity occurred in 65% of patients who received IMDELLTRA®, with

Grade 3 or higher events in 7% of patients including fatal events in 0.2%. The most frequent neurologic toxicities were dysgeusia (34%), headache (17%), peripheral neuropathy (9%), dizziness (9%), and insomnia (8%). The incidence of signs and symptoms consistent with ICANS was 10% in IMDELLTRA®-treated patients including events with the preferred terms: ICANS (4.7%), muscular weakness (3.2%), cognitive disorder (0.6%), aphasia (0.6%), depressed level of consciousness (0.4%), seizures (0.4%), encephalopathy (0.4%), and leukoencephalopathy (0.2%). There was one fatal reaction of ICANS. Recurrent ICANS occurred in 1.5% of patients. Of the patients who experienced ICANS, most experienced the event following Cycle 1 Day 1 (2.5%) and Cycle 1 Day 8 (3.6%). Following Day 1, Day 8, and Day 15 infusions, 1.3%, 1.3% and 0.4% of patients experienced Grade ≥ 2 ICANS, respectively. ICANS can occur several weeks following administration of IMDELLTRA®. The median time to onset of ICANS from the first dose of IMDELLTRA® was 16 days (range: 1 to 862 days). The median time to resolution of ICANS was 4 days (range: 1 to 40 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, until neurologic symptoms resolve.

Closely monitor patients for signs and symptoms of neurologic toxicity and ICANS during treatment with IMDELLTRA®. At the first sign of ICANS, immediately discontinue the infusion, 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, based on laboratory data, decreased neutrophils occurred in 16% of patients, including 9% Grade 3 or 4. The median time to onset for Grade 3 or 4 decreased neutrophil count was 41 days (range: 2 to 306 days). Decreased platelets occurred in 30% including 2.2% Grade 3 or 4. The median time to onset for Grade 3 or 4 decreased platelets was 67 days (range: 3 to 420 days). Decreased hemoglobin occurred in 56% of patients, including 4.7% Grade 3 or 4. Febrile neutropenia was reported as an adverse event in 1.5% of patients treated with IMDELLTRA®.

Monitor patients for signs and symptoms of cytopenias. Perform complete blood counts prior to treatment with all doses of IMDELLTRA®, up through Cycle 5 Day 15 and then prior to administration on Day 1 of each cycle starting with Cycle 6. 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 43% of patients who received IMDELLTRA®, including 14% Grade 3 or 4. The most frequent infections were pneumonia (11%), urinary tract infection (9%), COVID-19 (6%), upper respiratory tract infection (4.7%), respiratory tract infection (4%), candida infection (2.1%), oral candidiasis (2.1%), and nasopharyngitis (2.1%).

  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, based on laboratory data, elevated ALT occurred in 39% of patients who received IMDELLTRA®, including 2.5% with Grade 3 or 4 ALT. Elevated AST occurred in 43% of patients, including 3.2% Grade 3 or 4. Elevated bilirubin also occurred in 16% of patients, including 1.3% Grade 3 or 4. Liver enzyme elevation can occur with or without concurrent CRS.

  Monitor liver enzymes and bilirubin prior to treatment with IMDELLTRA®, 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 pooled safety population reflects exposure to intravenous IMDELLTRA®, as a single agent, at the recommended dosage of IMDELLTRA® 1 mg on Cycle 1 Day 1 followed by 10 mg on Days 8 and 15, and then every 2 weeks until disease progression or intolerable toxicity in 473 patients with small cell lung cancer enrolled in three clinical trials: DeLLphi-300, DeLLphi-301 and DeLLphi-304. Among 473 patients who received IMDELLTRA®, 40% were exposed for 6 months or longer and 19% were exposed for greater than one year.
- The most common (≥ 20%) adverse reactions were CRS (57%), fatigue (48%), decreased appetite (38%), dysgeusia (34%), pyrexia (33%), constipation (31%), musculoskeletal pain (31%), and nausea (25%).
- The most common (≥ 5%) Grade 3 or 4 laboratory abnormalities were decreased lymphocytes (43%), decreased sodium (12%), decreased total neutrophils (9%), and increased uric acid (6%).

DOSAGE AND ADMINISTRATION: Important Dosing Information

- Administer IMDELLTRA® as an intravenous infusion over 1 hour.
- Administer IMDELLTRA® according to the step-up dose and schedule in the IMDELLTRA® PI (Table 1) to reduce the incidence and severity of CRS.
- Evaluate complete blood count, liver enzymes and bilirubin prior to administration of all doses of IMDELLTRA® up through Cycle 5 Day 15 and then prior to administration of IMDELLTRA® on Day 1 of each cycle starting with Cycle 6. More frequent evaluation may be necessary if clinically indicated.
- For Cycle 1, administer recommended concomitant medications before and after Cycle 1 Day 1 and Cycle 1 Day 8 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 following 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 the start of the infusion with IMDELLTRA® following Cycle 1 Day 1 and Cycle 1 Day 8 doses, accompanied by a caregiver.
- Inform both the patient and the caregiver on the signs and symptoms of CRS and ICANS prior to discharge.
- Ensure patients are well hydrated prior to administration of IMDELLTRA®.

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

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, YouTube, and Threads.

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 BeOne Medicines Ltd. or Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast), our acquisitions of ChemoCentryx, Inc. or Horizon Therapeutics plc (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 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. 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, including those resulting from geopolitical relations and government actions. 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. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. 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. 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, 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. 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, 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 sustainability 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.

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