# EUROPEAN COMMISSION APPROVES AMGEN'S IMDYLLTRA® FOR THE TREATMENT OF EXTENSIVE-STAGE SMALL CELL LUNG CANCER

June 1, 2026

**Approval Based Upon Phase 3 DeLLphi-304 Trial Demonstrating 40% Reduction in Risk of Death with IMDYLLTRA Compared to Chemotherapy**

**Novel Treatment Option for Patients with Extensive-Stage Small Cell Lung Cancer That Has Progressed**

THOUSAND OAKS, Calif., June 1, 2026 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the European Commission (EC) has granted marketing authorization for IMDYLLTRA® (tarlatamab) as a monotherapy to treat adults with extensive-stage small cell lung cancer (ES-SCLC) who require systemic therapy following disease progression on or after first-line treatment with platinum-based chemotherapy.

The approval was based on results from DeLLphi-304, the first global Phase 3 trial to demonstrate a significant survival benefit over chemotherapy in this setting.1

"Small cell lung cancer is one of the most aggressive solid tumors, with high rates of relapse following first-line treatment and limited treatment options," said Jean-Charles Soria, senior vice president of Oncology at Amgen. "The European Commission's approval of IMDYLLTRA, the first and only T-cell engager therapy approved to treat small cell lung cancer, marks an important step forward for patients in Europe and reflects our commitment to advancing innovative medicines that can meaningfully improve outcomes for people living with this devastating disease."

DeLLphi-304, the global Phase 3 clinical trial, demonstrated that IMDYLLTRA 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; $P < 0.001$).1

"Patients with small cell lung cancer have historically faced a hard road when they progress after initial treatment, surviving only a few months," said Debra Montague, president, Lung Cancer Europe (LuCE). "Approval of a novel treatment option for people in Europe living with this challenging cancer represents meaningful progress and underscores the urgent need for innovation in lung cancer care."

The safety profile for IMDYLLTRA was consistent with its known profile. The most common adverse reactions were cytokine release syndrome (CRS) (56.7%), decreased appetite (36.4%), pyrexia (31.9%), dysgeusia (31.3%), constipation (30.4%), anaemia (30.0%), fatigue (29.8%), nausea (24.9%), asthenia (19.0%), neutropenia (16.9%), hyponatraemia (16.7%), headache (16.3%) and lymphopenia (15.6%). The most common serious adverse reactions were CRS (19.7%) and pyrexia (4.7%).

CRS primarily occurred after the first two doses. As reflected in the Summary of Product Characteristics (SmPC), patients should be monitored from the start of the IMDYLLTRA infusion for 6 to 8 hours on Cycle 1 Day 1 and Cycle 1 Day 8 in an appropriate healthcare setting.2

Amgen's robust IMDYLLTRA clinical development program includes the DeLLphi clinical trials, which evaluate IMDYLLTRA 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 IMDYLLTRA as a treatment for patients living with SCLC who progressed on or after one platinum-based chemotherapy regimen. Five hundred and nine patients were randomized to receive either IMDYLLTRA or local standard of care chemotherapy (topotecan in all countries except Japan; lurbinectedin in the U.S., Canada, Australia, Singapore, South Korea; and amrubicin in Japan). The primary outcome measure of the trial is OS. 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*.1,4

**About IMDELLTRA®/IMDYLLTRA® (tarlatamab)**
IMDYLLTRA 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. 5,6 DLL3 is a protein that is expressed on the surface of SCLC cells in up to 96% of patients with SCLC, but is minimally expressed on healthy cells, making it an exciting target.7,8

**About Small Cell Lung Cancer (SCLC)**
SCLC is one of the most aggressive and devastating forms of solid tumor cancer. Each year, SCLC accounts for approximately 13-15% of more than 2.4 million cases of lung cancer diagnosed worldwide.9-11 Despite initial high response rates to first-line platinum-based chemotherapy, most patients quickly relapse within months and require subsequent treatment options.10

**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-305, a randomized Phase 3 study comparing tarlatamab in combination with durvalumab vs. durvalumab alone in first-line ES-SCLC in the maintenance setting; 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, a B7-H3 targeting antibody drug conjugate, with or without anti-programmed death ligand 1 (PD-L1) in patients with ES-SCLC; DeLLphi-311, a Phase 1b study of tarlatamab in combination with etakafusp alfa (AB248), a novel CD8+ T-cell selective interleukin-2 (IL-2), in patients with ES-SCLC; DeLLphi-312, a randomized Phase 3 study evaluating tarlatamab in combination with

carboplatin, etoposide and durvalumab as an induction and maintenance therapy in first-line treatment of ES-SCLC; and DeLLphi-313, a Phase 1b study of tarlatamab in combination with zocilurtatug pelitecan, a DLL3 targeting antibody drug conjugate, with and without a PD-L1 inhibitor in patients with ES-SCLC.12

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

**About Amgen**
Amgen discovers, develops, manufactures and delivers innovative medicines to fight some of the world's toughest diseases. Harnessing the best of biology and technology, Amgen reaches millions of patients with its medicines.

More than 45 years ago, Amgen helped establish the biotechnology industry at its U.S. headquarters in Thousand Oaks, California, and it remains at the cutting edge of innovation, using technology and human genetic data to push beyond what is known today. Amgen is advancing a broad and deep pipeline and portfolio of medicines to treat cancer, inflammatory conditions, rare diseases, heart disease and obesity and obesity-related conditions.

Amgen has been consistently recognized for innovation and workplace culture, including honors from Fast Company and Forbes. 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, Facebook, TikTok and Threads.

**EU INDICATION**

IMDYLLTRA® (tarlatamab) is indicated as monotherapy for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC), who require systemic therapy following disease progression on or after first-line treatment with platinum-based chemotherapy.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

- **Cytokine Release Syndrome (CRS):** Administration of IMDYLLTRA® has been associated with CRS, including life-threatening or fatal events. In clinical trials with pooled safety data from 473 patients with SCLC receiving the IMDYLLTRA 1 mg as first dose and 10 mg second and later dose, CRS occurred in 56.7% of patients, with grade 1 in 39.3%, grade 2 in 15.4% of patients, grade 3 in 1.7% of patients and grade 4 events in 0.2% of patients. Serious events of CRS were reported in 19.7% of patients. After the first dose of IMDYLLTRA, 41.4% of patients experienced any grade CRS, with 34.0% of patients experiencing any grade CRS after the second dose. The majority of CRS events occurred after the first two doses, with 8.5% of patients experiencing CRS following third dose or later. Following the day 1 infusion, 13.7% of patients experienced ≥ grade 2 CRS. Following the day 8 infusion, 4.4% of patients experienced ≥ grade 2 CRS. The median time from the most recent dose of IMDYLLTRA to the first onset of CRS was 15.9 hours. For those grade 1 events that progressed to grade 2 or greater, the median time from grade 1 event to grade 2 or greater events was 22.1 hours. Cytokine release syndrome led to treatment interruption and/or dose modification in 2.1% of patients and to discontinuation of IMDYLLTRA in 0.6% of patients. Fatal CRS cases have been reported in the post-marketing setting.

  CRS may be associated with symptoms including pyrexia, hypotension, hypoxia, fatigue, tachycardia, headache, chills, nausea, and vomiting. Patients and caregivers should be advised of the potential for CRS onset after discharge and instructed to seek immediate medical attention if any signs or symptoms occur. IMDYLLTRA® should be administered in a healthcare facility equipped to monitor and manage CRS. It should be ensured that patients are euvolemic prior to initiating the infusions. Patients should be closely monitored for signs and symptoms of CRS during the initiation of IMDYLLTRA® treatment. To mitigate the risk of CRS, it is important to initiate IMDYLLTRA® at the recommended starting dose in Table 1 and managed according to the recommendations of Table 4 of the Summary of Product Characteristics (SmPC).
- **Immune effector cell-associated neurotoxicity syndrome (ICANS):** Administration of IMDYLLTRA® has been associated with ICANS, including life-threatening or fatal events (see section 4.8 of the SmPC). In clinical trials with pooled safety data from 473 patients with SCLC receiving IMDYLLTRA at 10 mg, ICANS was reported in 4.7% of patients. The median time from the first dose of IMDYLLTRA to the first onset of ICANS was 9.0 days. The median time to resolution of ICANS was 4 days. ICANS can occur up to several weeks following administration of IMDYLLTRA®. Adverse reactions that may be associated with ICANS include headache, encephalopathy, confusion, delirium, seizure, ataxia, neurotoxicity, and tremor. Patients should be closely monitored for signs and symptoms of ICANS during IMDYLLTRA® treatment. Patients and caregivers should be advised of the potential for ICANS onset after discharge and instructed to seek immediate medical attention if any signs or symptoms occur.

- **Neutropenia:** Administration of IMDYLLTRA® has been associated with neutropenia (see Section 4.8 of the SmPC). In clinical trials with pooled safety data from 473 patients with SCLC receiving IMDYLLTRA at 10 mg, neutropenia occurred in 16.9% of patients including 8.2% of patients experiencing grade 3 or grade 4 events. The median time from the first dose of IMDYLLTRA to the first onset of neutropenia was 43 days. Neutropenia leading to dose interruption occurred in 3.2% patients with none leading to treatment discontinuation. Treatment with G-CSF was required in 6% of patients. Patients should be closely monitored for signs and symptoms of neutropenia during IMDYLLTRA® treatment.
- **Infections**: Serious infections, including life-threatening and fatal infections, have been reported in patients treated with

IMDYLLTRA®. The most frequent infections include pneumonia, urinary tract infection, COVID-19, upper respiratory tract infection, respiratory tract infection, candida infection, oral candidiasis and nasopharyngitis. Patients should be monitored for signs and symptoms of infections prior to and during treatment with IMDYLLTRA®.

- **Hypersensitivity**: Hypersensitivity reactions have been reported in patients treated with IMDYLLTRA® including rare severe events. Clinical signs and symptoms of hypersensitivity may include but are not limited to rash and bronchospasm. Patients should be monitored for signs and symptoms of hypersensitivity during treatment with IMDYLLTRA® and managed as clinically indicated. It should be considered to withhold or to permanently discontinue IMDYLLTRA® based on severity (see Table 6 of the SmPC for management of other adverse reactions).
- **Hepatotoxicity:** Administration of IMDYLLTRA® has been associated with elevated liver enzymes. Liver enzyme elevation can occur with or without concurrent CRS. Liver enzymes and bilirubin should be monitored prior to treatment with IMDYLLTRA®, and as clinically indicated. Potential toxicities should be managed according to the recommendations in Table 6 of the SmPC.
- **Women of childbearing potential/contraception:** Pregnancy status of females of child bearing potential should be verified prior to initiating treatment with IMDYLLTRA®. Females of reproductive potential have to use effective contraception during treatment and for 2 months after the last dose of IMDYLLTRA® (see Section 4.6 of the SmPC).

- **Excipients with known effect:** This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'. This medicinal product contains 0.04 mg of polysorbate 80 in each 1 mg vial and 0.2 mg in each 10 mg vial. Polysorbates may cause allergic reactions.

**ADVERSE REACTIONS**

- The safety profile for IMDYLLTRA was consistent with its known profile. The most common adverse reactions were cytokine release syndrome (CRS) (56.7%), decreased appetite (36.4%), pyrexia (31.9%), dysgeusia (31.3%), constipation (30.4%), anaemia (30.0%), fatigue (29.8%), nausea (24.9%), asthenia (19.0%), neutropenia (16.9%), hyponatraemia (16.7%), headache (16.3%) and lymphopenia (15.6%). The most common serious adverse reactions were CRS (19.7%) and pyrexia (4.7%).

**DOSAGE AND ADMINISTRATION: Important Dosing Information**

- IMDYLLTRA treatment should be initiated under the direction of and supervised by physicians experienced in the use of cancer therapy. It should be administered in an appropriate healthcare facility.
- The recommended dosing schedule of IMDYLLTRA is an initial dose of 1 mg on day 1 followed by 10 mg on days 8, 15, and every 2 weeks thereafter (as shown in Table 1 of the SmPC).
- Patients should be monitored from the start of the infusion for 6 to 8 hours on day 1 and day 8. Additional monitoring and monitoring on subsequent infusions is at the discretion of the physician.
- On day 1 and day 8, patients should be instructed to remain within proximity of an appropriate healthcare facility for 24 hours starting from each infusion, accompanied by a caregiver.
- Patients should be treated until disease progression or unacceptable toxicity.
- Both patients and caregivers should be informed on signs and symptoms of CRS and ICANS prior to discharge.

**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 in the United States.

**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 U.S. IMDELLTRA® full Prescribing Information, including BOXED WARNINGS.**

**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 BeOne Medicines Ltd.), the performance of Otezla® (apremilast), our acquisitions of ChemoCentryx, Inc., Dark Blue Therapeutics, Ltd. 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. 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, 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. 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. 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, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions. 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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**REFERENCES**

1. Mountzios G, Sun L, Cho BC, et al. Tarlatamab in small-cell lung cancer after platinum-based chemotherapy. N Engl J Med. 2025;393(4):349-361.
2. Amgen. (2026) Imdylltra 1 mg and 10 mg powder for concentrate and solution for infusion: Summary of product characteristics. European Medicines Agency. https://www.ema.europa.eu
3. ClinicalTrials.gov. DeLLphi-304 clinical trial listing. Accessed April 2026. https://www.clinicaltrials.gov/study/NCT05740566.
4. Rudin CM, Mountzios GS, Sun L, et al. Tarlatamab versus chemotherapy (CTx) as second-line (2L) treatment for small-cell lung cancer: primary analysis of Ph3 DeLLphi-304. Oral presentation at: ASCO Annual Meeting; 30 May–3 June, 2025; Chicago, IL. Abstract LBA8008.

5. 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(5):1526-1537.
6. Baeuerle PA, Kufer P, Bargou R. BiTE: Teaching antibodies to engage T-cells for cancer therapy. Curr Opin Mol Ther. 2009;11(1):22-30.
7. Ahn MJ, Cho BC, Felip E, et al. Tarlatamab for patients with previously treated small-cell lung cancer. N Engl J Med. 2023;389(22):2063-2075.
8. 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.
9. International Agency for Research on Cancer. GLOBOCAN 2022: Trachea, bronchus and lung fact sheet. Accessed April 2026. https://gco.iarc.who.int/media/globocan/factsheets/cancers/15-trachea-bronchus-and-lung-fact-sheet.pdf.
10. Oronsky B, Abrouk N, Caroen S, et al. A 2022 update on extensive stage small-cell lung cancer (SCLC). J Cancer. 2022;13(9):2945-2953.
11. Sabari JK, Lok BH, Laird JH, et al. Unravelling the biology of SCLC: implications for therapy. Nat Rev Clin Oncol. 2017;14(9):549-561.
12. ClinicalTrials.gov. Tarlatamab clinical trial listings. US National Library of Medicine. Accessed April 2026. https://www.clinicaltrials.gov.

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