



FDA APPROVES REDUCED MONITORING TIME FOR FIRST TWO DOSES OF IMDELLTRA®

September 14, 2026

Update Supports Broader Access to IMDELLTRA in Community Settings for People Living with Extensive-Stage Small Cell Lung Cancer

THOUSAND OAKS, Calif., Sept. 14, 2026 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) approved an update to the IMDELLTRA® (tarlatamab-dlle) Prescribing Information that substantially reduces the recommended monitoring time for the first two doses of treatment in an appropriate healthcare setting.

This approval means that patients receiving IMDELLTRA should now be monitored for 6 to 8 hours from the start of their first two infusions, compared with the previously recommended 22 to 24 hours. Patients will also receive a follow-up assessment, including vital signs, the day after each of these first two doses.

For people living with extensive-stage small cell lung cancer (ES-SCLC), the change could mean substantially less time spent in a healthcare setting during the initial treatment period. The updated requirement may also reduce treatment complexity for community oncology practices, where an estimated 80% to 85% of U.S. cancer patients receive care.¹

"People being treated for small cell lung cancer are already navigating an aggressive and difficult-to-treat disease, and the time required to receive and monitor treatment can add to that burden for both patients and care centers," said Jay Bradner, M.D., executive vice president, Research and Development, Artificial Intelligence and Data at Amgen. "This approval is an important step in simplifying care for people living with and treating ES-SCLC. Reducing monitoring to 6-8 hours for the initial doses may help address practical barriers associated with administering IMDELLTRA and enable more patients to receive care closer to home. We continue to work closely with the healthcare community to ensure appropriate educational support for navigating IMDELLTRA treatment is available to providers, patients and care partners."

"In community oncology, we care for patients where they live, and for people living with small cell lung cancer, that matters," said David M. Waterhouse, MD, MPH, FASCO, medical oncologist/hematologist at Oncology Hematology Care in Cincinnati, OH. "These patients are often very sick, and traveling long distances or spending extended time in a healthcare setting can be difficult for them and their families. Reducing the required monitoring period may make IMDELLTRA more feasible to administer in community practices, helping more patients receive treatment in their local care network and spend less time away from their support systems."

ES-SCLC is an aggressive form of lung cancer in which most patients experience disease progression following first-line treatment.² The scope of the label update was limited to the first two doses, which now recommends only 6 to 8 hours of monitoring from the start of infusion in an appropriate healthcare setting. Beyond the update to the first two doses and the addition of a patient assessment following those initial doses, the monitoring and supportive care recommendations remain unchanged: 6-8 hours of monitoring following the third dose (Cycle 1 Day 15) and throughout Cycle 2, decreasing to 3-4 hours for Cycles 3-4 and 2 hours for Cycle 5 and subsequent doses. It is recommended 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. Patients will also receive a follow-up assessment, including vital signs, the day after each of these first two doses on Cycle 1, Days 2 and 9.

The updated monitoring requirements represent an important evolution in the administration of IMDELLTRA and reinforce Amgen's commitment to advancing treatments while addressing the real-world needs of people living with cancer.

Amgen recently announced [landmark positive topline overall survival data](#) from the Phase 3 DeLLphi-305 study in first-line ES-SCLC. Reduced post-infusion monitoring timing is being evaluated in several ongoing studies across indications and lines of therapy which will continue to inform the potential to further reduce monitoring approaches in the future.

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 2.6 million cases of lung cancer diagnosed worldwide.²⁻⁴ Despite initial high response rates to first-line platinum-based chemotherapy, most patients quickly relapse within months and require subsequent treatment options.²

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.^{5,6} 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.^{7,8}

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.

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 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 and after treatment with IMDELLTRA®. At the first sign of CRS during treatment, immediately discontinue IMDELLTRA® infusion. If CRS occurs during or after treatment, evaluate the patient for hospitalization and manage based on severity. Withhold or permanently discontinue IMDELLTRA® based on severity. Counsel patients and caregivers to seek immediate medical attention should signs or symptoms of CRS occur after discharge.

- **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 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 6 to 8 hours following Cycle 1 Day 1 and Cycle 1 Day 8 in an appropriate healthcare setting.
- Perform patient assessment including vital signs check on Cycle 1 Days 2 and 9.
- 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 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.

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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.

Any scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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