# IMDELLTRA™ FACT SHEET

**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).**

1 mg package (NDC 55513-059-01)[1]


- **1 single-dose vial of 1 mg IMDELLTRA™** (NDC 55513-103-01)[1,2]
- **2 vials of 7 mL IV Solution Stabilizer (IVSS)** (NDC 55513-068-01)[1,2]

10 mg package (NDC 55513-077-01)[1]


- **1 single-dose vial of 10 mg IMDELLTRA™** (NDC 55513-069-01)[1,2]
- **2 vials of 7 mL IV Solution Stabilizer (IVSS)** (NDC 55513-068-01)[1,2]

## Breakthrough, durable efficacy in the DeLLphi-301* trial[1]

**Primary endpoint:**
**Overall response rate (ORR)[1,3,†,‡]**

**40%**

n=40/99 (95% CI: 31-51)

**2% CR** (n=2/99) | **38% PR** (n=38/99)

**Secondary endpoint:**
**Median duration of response (mDOR)[1,3,‡,§,**]**

**9.7 months**

(2.7–20.7+ months)

**68%** (n=27/40)
**responded for ≥ 6 months††**

**Secondary endpoint:**
**Median progression-free survival (mPFS)[3,‡‡]**

**4.9 months**

n=100
(95% CI: 2.9–6.7)

**Secondary endpoint:**
**Median overall survival (mOS)[3,‡‡]**

**14.3 months**

n=100
(95% CI: 10.8–NE)

Treatment effects for this study on time-based endpoints, such as PFS and OS, can be difficult to interpret in the absence of a comparator arm.

*DeLLphi-301 was a phase 2, open-label, multicenter, multi-cohort clinical trial evaluating IMDELLTRA™ 10 mg in 99 patients with 3L+ ES-SCLC, with disease progression after previous treatment with platinum-based chemotherapy and at least one other line of prior therapy.[1,3]

†Based on 99 patients in the DeLLphi-301 study who received at least 1 dose of IMDELLTRA™ 10 mg and had measurable disease at baseline per blinded independent central review (BICR).[1] ‡Assessed by BICR.[1] §Based on 40 patients in the DeLLphi-301 study who received at least 1 dose of IMDELLTRA™ 10 mg, had measurable disease at baseline per BICR, and responded to treatment.[1] **Median based on Kaplan-Meier estimate.[1] ††Based on observed duration of response.[1] ‡‡Based on 100 patients who were assigned to receive IMDELLTRA™ 10 mg in the DeLLphi-301 study (intention-to-treat population).[3]

3L, third line; CI, confidence interval; CR, complete response; DCR, disease control rate; IV, intravenous; NDC, National Drug Code; OS, overall survival; PFS, progression-free survival; PR, partial response.

## 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.**

**Please see additional Important Safety Information, including BOXED WARNINGS, inside.**

IMDELLTRA™
(tarlatamab-dlle) for injection
1 mg & 10 mg single-use vials

## Product Information

| Package NDC[1] | Strength[1] | IMDELLTRA™ for injection is a sterile, preservative free, white to slightly yellow, lyophilized powder in a single-dose vial supplied in package as follows:[1] |
|---|---|---|
| 55513-059-01 | 1 mg | • 1 single-dose vial of 1 mg IMDELLTRA™ (NDC 55513-103-01)[1,2]<br>• 2 vials of 7 mL IVSS (NDC 55513-068-01)[1,2] |
| 55513-077-01 | 10 mg | • 1 single-dose vial of 10 mg IMDELLTRA™ (NDC 55513-069-01)[1,2]<br>• 2 vials of 7 mL IVSS (NDC 55513-068-01)[1,2] |

**Do not use IVSS for reconstitution of IMDELLTRA™.** The IVSS is used to coat the IV bag prior to addition of reconstituted IMDELLTRA™ to prevent adsorption of IMDELLTRA™ to IV bags and IV tubing.[1]

### Product expiration/ shelf life

The expiration date is printed on each dispensing pack and vial label.

### Storage and handling of IMDELLTRA™ and IVSS vials

- Store IMDELLTRA™ and IVSS vials refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. Do not freeze[1]
- IMDELLTRA™ and IVSS vials may be kept at room temperature between 20°C to 25°C (68°F to 77°F) for up to 24 hours in the original carton to protect from light[1]

### Product returns

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at **1-800-28-AMGEN** (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

Supplied and marketed by Amgen Inc. (1-800-282-6436) www.amgen.com

**For dosing, administration, and preparation information, please see the IMDELLTRA™ Dosing, Administration & Pharmacy Guide and refer to the full Prescribing Information**

### IMDELLTRA™ specialty distribution

| Specialty Distributor | Phone Number | Website |
|---|---|---|
| ASD Healthcare | 800-746-6273 | www.asdhealthcare.com |
| Oncology Supply | 800-633-7555 | www.oncologysupply.com |
| Cardinal Health SPD–Hospital & SP's | 855-855-0708 | www.cardinalhealth.com |
| Cardinal Health SPD–Clinics | 877-453-3972 | www.cardinalhealth.com |
| Cardinal Health Puerto Rico 120, Inc. | 787-625-4100 | www.cardinalhealth.pr |
| McKesson Plasma and Biologics | 877-625-2566 | connect.mckesson.com |
| McKesson Specialty Care Distribution | 855-477-9800 | mscs.mckesson.com/CustomerCenter |
| CuraScript Specialty Distribution | 877-599-7748 | www.curascript.com |

**For questions on coverage, co-pay assistance, and reimbursement:**
**Amgen® SupportPlus: 1-866-264-2778** or **AmgenSupportPlus.com**

IV, intravenous; IVSS, IV solution stabilizer; NDC, National Drug Code; SP, specialty pharmacy; SPD, specialty pharmaceutical distribution.

**Please see additional Important Safety Information, including BOXED WARNINGS.**

# AMGEN® Support+

## We're right here, right when you need us

### HCP Support Center

**Our Amgen SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.**

**Benefits Verification**
- Verify patient's insurance plan coverage details

**Prior Authorization Requirements**
- Provide payer-specific prior authorization forms

**Amgen SupportPlus Customer Portal**
- A tool for managing patient benefits verification and more
- Submit, store, and retrieve benefit verifications electronically

### Amgen® Patient Navigator

**A single point of contact to help answer questions about access and reimbursement, navigating treatment logistics, and to provide supplemental resources as your patients transition from hospital to outpatient care.**

**Amgen Patient Navigators can help with:**
- Benefits verification and understanding coverage
- Prior authorization process
- Reimbursement and access resources

**Visit AmgenSupportPlus.com to learn how an Amgen Patient Navigator can help.**
**Call Amgen SupportPlus at (866) 264-2778, Monday – Friday 9:00 AM – 8:00 PM ET**

The Amgen Patient Navigator is not part of a patient's treatment team and does not provide medical advice or case management services. The Amgen Patient Navigator does not administer Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.


AMGEN Support+ | **Co-Pay Program**

### Helping eligible patients save on out-of-pocket costs

**The Amgen SupportPlus Co-Pay Program may help eligible patients with private or commercial insurance lower their out-of-pocket costs.**

- Pay as little as $0* out-of-pocket for each dose
- Can be applied to deductible, co-insurance, and co-payment*
- No income eligibility requirement

**Encourage your patients with private or commercial insurance to check eligibility and enroll.**

Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

**What if my patient doesn't have private or commercial insurance?**

Amgen SupportPlus can provide your patients with information about independent nonprofit foundations that may be able to help.†

*Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

†Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofit's criteria. Amgen has no control over these programs and provides information as a courtesy only.

Call **Amgen SupportPlus** at **(866) 264-2778**, Monday – Friday 9:00 AM – 8:00 PM ET.
Visit **AmgenSupportPlus.com** to learn how Amgen can help.

HCP, healthcare professional.

## 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.

## IMPORTANT SAFETY INFORMATION (CONT'D)

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.**

IMDELLTRA™
(tarlatamab-dlle) for injection 1 mg & 10 mg single-use vials

Visit IMDELLTRAhcp.com to learn more

**References: 1.** IMDELLTRA™ (tarlatamab-dlle) prescribing information, Amgen. **2.** Data on file, Amgen; 2024. **3.** Ahn M-J, et al. *N Engl J Med.* 2023;389:2063-2075.

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