Join us at Cleveland Clinic Cancer Conference 2026 for an informative presentation focused on Extensive Stage Small Cell Lung Cancer (ES-SCLC) and IMDELLTRA® (tarlatamab-dlle)

The First and Only DLL3-Targeting Bispecific T-cell Engager (BiTE®) Therapy for 2L ES-SCLC

Speaker

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Elliston Place Plaza – Medical Oncology & Hematology

Nashville – Saint Thomas West Clinic

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12:30 – 1:15 pm EST

Margaritaville Hollywood Beach Resort

Hemisphere Dancer, 9th floor

1111 N Ocean Drive, Hollywood, FL 33019

Lunch to be served

This program/event is developed and offered by Amgen. This is not an official program/event of the Cleveland Clinic

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%),

Please see additional Important Safety Information on the following page.

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

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 accompanying IMDELLTRA® full Prescribing Information, including BOXED WARNINGS.

Reference: IMDELLTRA® (tarlatamab-dlle) prescribing information, Amgen.
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