MEDICATION GUIDE
IMDELLTRA™ (im del trah)
(tarlatamab-dlle)
for injection, for intravenous use

What is the most important information I should know about IMDELLTRA?

IMDELLTRA may cause serious side effects, including:

- **Cytokine Release Syndrome (CRS).** CRS is common during treatment with IMDELLTRA and can also be serious or life-threatening. Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS, including:
  - fever of 100.4°F (38°C) or higher
  - low blood pressure
  - tiredness
  - fast heartbeat or dizziness
  - headache
  - shortness of breath or trouble breathing
  - nausea and vomiting
  - confusion, restlessness, or feeling anxious
  - problems with balance and movement, such as trouble walking
  - heart, liver, or kidney problems
  - unusual bleeding or bleeding that lasts a long time

  Due to the risk of CRS, you will receive IMDELLTRA on a "step-up dosing schedule":
  - The step-up dosing schedule is when you receive a smaller dose of IMDELLTRA on Day 1 of your first treatment cycle (Cycle 1).
  - You will receive the full treatment dose of IMDELLTRA on Day 8 and Day 15 of Cycle 1. You will receive the full treatment dose 1 time every 2 weeks after Day 15 of Cycle 1.
  - If your dose of IMDELLTRA is delayed for any reason, you may need to repeat the "step-up dosing schedule".
  - Before receiving your Day 1 and Day 8 doses of Cycle 1 of IMDELLTRA, you will be given a medicine to help reduce your risk of CRS. This will be given into your vein by intravenous (IV) infusion. You will also receive IV fluids after each of your Cycle 1 doses of IMDELLTRA (on Day 1, Day 8, and Day 15). Your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses.
  - See **"How will I receive IMDELLTRA?"** for more information about how you will receive IMDELLTRA.
- **Neurologic Problems.** IMDELLTRA can cause neurologic problems that can be serious or life-threatening. Neurologic problems may happen days or weeks after you receive IMDELLTRA. Your healthcare provider may refer you to a healthcare provider who specializes in neurologic problems. Tell your healthcare provider right away if you develop any signs or symptoms of neurologic problems, including:
  - trouble speaking, memory loss, or personality changes
  - confusion, feeling disoriented, slow thinking, or not being able to think clearly
  - seizure
  - problems with walking, or loss of balance or coordination
  - weakness or numbness of your arms or legs
  - shaking (tremors)
  - headache
  - numbness or tingling of your hands or feet
  - trouble sleeping
  - fainting or loss of consciousness
  - feeling like you have no energy

Due to the risk of CRS and neurologic problems you will receive the following monitoring during treatment with IMDELLTRA:

- **For Day 1 and Day 8 of Cycle 1 doses**, your healthcare provider will monitor you **for 22 to 24 hours from the start of the IMDELLTRA infusion in an appropriate healthcare setting** that can manage these side effects. **You should remain within 1 hour of an appropriate healthcare setting for a total of 48 hours** from the start of the IMDELLTRA infusion after your Day 1 and Day 8 of Cycle 1 doses **and be accompanied by a caregiver**.
- **For Day 15 of Cycle 1 and Cycle 2 doses**, your healthcare provider will watch you **for 6 to 8 hours** after the IMDELLTRA infusion.
- **For Cycle 3 and Cycle 4 doses**, your healthcare provider will watch you **for 3 to 4 hours** after the IMDELLTRA infusion.
- **For Cycle 5 and later doses**, your healthcare provider will watch you **for 2 hours** after the IMDELLTRA infusion.

Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems during treatment with IMDELLTRA, as well as other side effects, and treat you as needed. You may be hospitalized if you develop signs or symptoms of CRS or neurologic problems during treatment with IMDELLTRA. Your healthcare provider may temporarily stop or completely stop your treatment with IMDELLTRA if you develop CRS, neurologic problems, or any other side effects that are severe.

See **"What are the possible side effects of IMDELLTRA?"** for more information about side effects.

What is IMDELLTRA?

IMDELLTRA is a prescription medicine used to treat adults with extensive stage small cell lung cancer (ES-SCLC), which is cancer that has spread throughout the lung or to other parts of the body, **and**
who have received treatment with chemotherapy that contains platinum, and it did not work or is no longer working.

It is not known if IMDELLTRA is safe and effective in children.

Before receiving IMDELLTRA, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- are pregnant or plan to become pregnant. IMDELLTRA may harm your unborn baby.
  Females who are able to become pregnant:
  - Your healthcare provider should do a pregnancy test before you start treatment with IMDELLTRA.
  - You should use an effective form of birth control (contraception) during treatment with IMDELLTRA, and for 2 months after your last dose of IMDELLTRA.
  - Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with IMDELLTRA.
- are breastfeeding or plan to breastfeed. It is not known if IMDELLTRA passes into your breast milk. Do not breastfeed during treatment with IMDELLTRA and for 2 months after the last dose of IMDELLTRA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive IMDELLTRA?

- IMDELLTRA will be given to you by your healthcare provider by intravenous (IV) infusion through a needle placed in a vein. The infusion will take about 1 hour.
- Your IMDELLTRA treatment schedule is divided into cycles that are usually 28 days (4 weeks) long.
- Your healthcare provider will decide how many treatment cycles you will receive.
- See **"What is the most important information I should know about IMDELLTRA?"** for more information about how you will receive IMDELLTRA.

What should I avoid while receiving IMDELLTRA?

Do not drive, operate heavy or potentially dangerous machinery or do other dangerous activities, including work-related activities, during treatment with IMDELLTRA if you develop dizziness, confusion, tremors, sleepiness, or any other symptoms that impair consciousness until your signs and symptoms go away. These may be signs and symptoms of neurologic problems. See "**What is the most important information I should know about IMDELLTRA**" for more information about signs and symptoms of neurologic problems.

What are the possible side effects of IMDELLTRA?

IMDELLTRA may cause serious side effects, including:

- See **"What is the most important information I should know about IMDELLTRA?"**
- **Low blood cell counts (cytopenia).** Decreased blood cell counts are common with IMDELLTRA and can also be severe. IMDELLTRA may cause the following low blood cell counts:
  - low white blood cell counts (neutropenia). Low white blood cells can increase your risk for infection.
  - low red blood cell counts (anemia). Low red blood cells can cause tiredness and shortness of breath.
  - low platelet counts (thrombocytopenia). Low platelet counts can cause bruising or bleeding problems.
- **Infections.** IMDELLTRA can cause serious infections that can be life-threatening and may lead to death. Your healthcare provider will check you for signs and symptoms of infection before and during treatment with IMDELLTRA. Tell your healthcare provider right away if you develop any signs or symptoms of infection during treatment with IMDELLTRA, including:
  - fever of 100.4°F (38°C) or higher
  - cough
  - chest pain
  - tiredness
  - shortness of breath
  - painful rash
  - sore throat
  - pain during urination
  - feeling weak or generally unwell
- **Liver problems.** IMDELLTRA can cause increased liver enzymes and bilirubin in your blood. These increases can happen with or without you also having CRS. Tell your healthcare provider if you develop any signs or symptoms of liver problems, including:
  - tiredness
  - loss of appetite
  - pain in your right upper stomach-area (abdomen)
  - dark urine
  - yellowing of your skin or the white part of your eyes
- **Allergic reactions.** IMDELLTRA can cause allergic reactions that can be severe. Go to the nearest emergency room or get medical help right away if you develop any signs or symptoms of a severe allergic reaction during treatment with IMDELLTRA, including:
  - shortness of breath or trouble breathing
  - pain or tightness in your chest and back
  - wheezing
  - coughing
  - feeling lightheaded or dizzy
  - rash

Your healthcare provider will do bloodwork before you start and during treatment with IMDELLTRA. Your healthcare provider will monitor you for signs or symptoms of these serious side effects during treatment and may temporarily or completely stop treatment with IMDELLTRA if you develop certain serious side effects.

The most common side effects of IMDELLTRA also include:

- tiredness
- fever
- a bad or metallic taste in your mouth
- decreased appetite
- muscle or bone pain
- constipation
- nausea

The most common severe abnormal lab test results with IMDELLTRA include: decreased white blood cells, decreased sodium, increased uric acid, decreased red blood cells, increased blood clotting time, decreased potassium, increased liver enzymes, and decreased platelets.

These are not all of the possible side effects of IMDELLTRA.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of IMDELLTRA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about IMDELLTRA that is written for health professionals.

What are the ingredients in IMDELLTRA?

Active ingredients: tarlatamab-dlle
Inactive ingredients: glutamic acid, polysorbate 80, sucrose, and sodium hydroxide.
Inactive ingredients of IV Solution Stabilizer: citric acid monohydrate, lysine hydrochloride, polysorbate 80, sodium hydroxide and water for Injection.

Manufactured by: Amgen Inc., One Amgen Center Drive, Thousand Oaks, CA 91320-1799
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For more information, go to www.imdelltra.com or call Amgen at 1-800-772-6436.

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