MEDICATION GUIDE
LYNOZYFIC™ (lin-oh-ZI-fik)
(linvoseltamab-gcpt)
injection, for intravenous use

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

LYNOZYFIC may cause serious or life-threatening side effects, including:

- **Cytokine Release Syndrome (CRS) and infusion related reactions (IRR)**. CRS is common during treatment with LYNOZYFIC 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 or IRR, including:
  - fever of 100.4ºF (38ºC) or higher
  - chills or shaking
  - trouble breathing
  - fast heartbeat
  - dizziness or light-headedness
- **Neurologic problems.** LYNOZYFIC can cause neurologic problems that can be serious or life-threatening. Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of neurologic problems, including:
  - headache
  - agitation, trouble staying awake, confusion or disorientation, seeing or hearing things that are not real (hallucinations)
  - trouble speaking, writing, thinking, remembering things, paying attention, or understanding things
  - problems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasms
  - numbness and tingling (feeling like “pins and needles”)
  - burning, throbbing, or stabbing pain
  - changes in your handwriting
  - seizures

Due to the risk of CRS and neurologic problems, you will receive LYNOZYFIC on a “step-up dosing schedule” and should be hospitalized for 24 hours after the first and second “step-up” doses.

- During the “step-up dosing schedule”:
  - For your first dose, you will receive a smaller “step-up” dose of LYNOZYFIC on Day 1 of your treatment.
  - For your second dose, you will receive a larger “step-up” dose of LYNOZYFIC, which is usually given on Day 8 of your treatment.
  - For your third dose, you will receive the first treatment dose of LYNOZYFIC, which is usually given on Day 15 of your treatment.
- Your healthcare provider may repeat one or both of the “step-up” doses depending on side effects or if your treatment is delayed.
- Before the “step-up” doses and the first two treatment doses of LYNOZYFIC, you will receive medicines to help reduce your risk of CRS and IRR. Your healthcare provider will decide if you need to receive medicine to help reduce your risk of side effects with future doses.
- See **“How will I receive LYNOZYFIC?”** for more information about how you will receive LYNOZYFIC.

- **LYNOZYFIC is available only through the LYNOZYFIC Risk Evaluation and Mitigation Strategy (REMS) due to the risk of side effects of CRS and neurologic problems.** You will receive a Patient Wallet Card from your healthcare provider. **Carry the LYNOZYFIC Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The LYNOZYFIC Patient Wallet Card lists signs and symptoms of CRS and neurologic problems. **Get medical help right away if you develop any of the signs and symptoms listed on the LYNOZYFIC Patient Wallet Card**. You may need to be treated in a hospital.

Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems during treatment with LYNOZYFIC, as well as other side effects, and may treat you in a hospital if needed. Your healthcare provider may temporarily stop or completely stop your treatment with LYNOZYFIC if you develop CRS, neurologic problems, or any other severe side effects.

If you have any questions about LYNOZYFIC, ask your healthcare provider.

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

What is LYNOZYFIC?

LYNOZYFIC is a prescription medicine used to treat adults with multiple myeloma who:

- have already received at least 4 treatment regimens, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody to treat their multiple myeloma, **and**
- their cancer has come back or did not respond to prior treatment.

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

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

- have an infection.
- are pregnant or plan to become pregnant. LYNOZYFIC may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with LYNOZYFIC.

  Females who are able to become pregnant:

  - Your healthcare provider should do a pregnancy test before you start treatment with LYNOZYFIC.
  - You should use an effective form of birth control (contraception) during treatment with LYNOZYFIC and for 3 months after your last dose of LYNOZYFIC.
- are breastfeeding or plan to breastfeed. It is not known whether LYNOZYFIC passes into your breast milk. Do not breastfeed during treatment with LYNOZYFIC and for 3 months after your last dose of LYNOZYFIC.

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 LYNOZYFIC?

- LYNOZYFIC will be given to you by your healthcare provider by infusion through a needle placed in a vein (intravenous infusion).
- See **"What is the most important information I should know about LYNOZYFIC?"** for more information about how you will receive LYNOZYFIC.
- After the "step-up dosing schedule", the treatment dose of LYNOZYFIC is usually given 1 time each week for 11 doses, and then 1 time every other week for 5 doses. After these doses and based on how your disease responds, your healthcare provider will decide if you are able to receive LYNOZYFIC less often (every 4 weeks) or will continue to have every other week treatment.
- Your healthcare provider will decide how long you will receive treatment with LYNOZYFIC.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment. It is important for you to be monitored closely for side effects during treatment with LYNOZYFIC.

What should I avoid while receiving LYNOZYFIC?

Do not drive, or operate heavy or potentially dangerous machinery, or do other dangerous activities for 48 hours after completing each of your "step-up" doses or at any time during treatment with LYNOZYFIC if you develop new neurologic symptoms, until the symptoms go away.

See **"What is the most important information I should know about LYNOZYFIC?"** for more information about signs and symptoms of neurologic problems.

What are the possible side effects of LYNOZYFIC?
LYNOZYFIC may cause serious side effects, including:

- See **"What is the most important information I should know about LYNOZYFIC?"**
- **Infections.** LYNOZYFIC can cause bacterial, viral, or fungal infections that are serious, life-threatening, or that may lead to death. Upper respiratory tract infections and pneumonia are common during treatment with LYNOZYFIC.
  - Your healthcare provider will monitor you for signs and symptoms of infection before and during treatment with LYNOZYFIC.
  - Your healthcare provider may prescribe medicines for you to help prevent infections and treat you as needed if you develop an infection during treatment with LYNOZYFIC.
  - Tell your healthcare provider right away if you develop any signs or symptoms of infection during treatment with LYNOZYFIC, including:
    - fever of 100.4 °F (38 °C) or higher
    - chills
    - cough
    - shortness of breath
    - chest pain
    - sore throat
    - pain during urination
    - feeling weak or generally unwell
- **Decreased white blood cell counts.** Decreased white blood cell counts are common during treatment with LYNOZYFIC and can also be severe. Fever can happen with low white blood cell counts and may be a sign that you have an infection. Your healthcare provider will check your blood cell counts before you start treatment and during treatment with LYNOZYFIC, and will treat you as needed.
- **Liver problems.** LYNOZYFIC can cause increased liver enzymes and bilirubin in your blood. These increases can happen with or without you also having CRS. Your healthcare provider will do blood tests to check your liver before starting and during treatment with LYNOZYFIC. Tell your healthcare provider if you develop any of the following signs or symptoms of liver problems:
  - 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

The most common side effects of LYNOZYFIC include:

- muscle and bone pain
- cough
- diarrhea
- tiredness or weakness
- nausea
- headache
- shortness of breath

The most common severe abnormal blood test results with LYNOZYFIC include: low white blood cell counts and low red blood cell counts.

These are not all of the possible side effects of LYNOZYFIC.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about safe and effective use of LYNOZYFIC

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 LYNOZYFIC that is written for health professionals.

What are the ingredients in LYNOZYFIC?

Active ingredient: linvoseltamab-gcpt

Inactive ingredients: histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, and Water for Injection.

Manufactured by: Regeneron Pharmaceuticals, Inc., Tarrytown, NY 10591 U.S. License No. 1760

For more information about LYNOZYFIC, go to www.LYNOZYFIC.com or call 1-844-746-4363.

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