LYNOZYFIC™
(linvoseltamab-gcpt) Injection 5mg | 200mg

FDA-Required REMS Safety Information

- Risk of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS) with LYNOZYFIC
- Required REMS certification to prescribe LYNOZYFIC

Dear Healthcare Provider,

The purpose of this letter is to inform you of important safety information for LYNOZYFIC based on current Prescribing Information. FDA has required this safety notice as part of the LYNOZYFIC REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform you about the serious risks of CRS and neurologic toxicity, including ICANS.

Serious Risks of LYNOZYFIC

- **CRS**, including serious or life-threatening reactions, can occur in patients receiving LYNOZYFIC.
  - Initiate treatment with LYNOZYFIC step-up dosing to reduce the risk of CRS.
  - Manage CRS, withhold LYNOZYFIC until CRS resolves, and modify the next dose or permanently discontinue based on severity.
- **Neurologic toxicity, including ICANS**, including serious or life-threatening reactions, can occur in patients receiving LYNOZYFIC.
  - Monitor patients for signs or symptoms of neurologic toxicity, including ICANS during treatment.
  - Manage neurologic toxicity, including ICANS, withhold LYNOZYFIC until neurologic toxicity, including ICANS resolves, and modify the next dose or permanently discontinue based on severity.

Enclosed for your review and awareness of these serious risks is the LYNOZYFIC **REMS Fact Sheet**, a non-promotional Fact Sheet reviewed by the FDA, which will provide you with more information about these risks and the LYNOZYFIC REMS requirements.

REMS Requirements

- LYNOZYFIC can only be prescribed and/or dispensed by certified prescribers and certified pharmacies and healthcare settings.
- Those who prescribe and/or dispense LYNOZYFIC must be aware of how to manage the risks of CRS and neurologic toxicity, including ICANS.
- Prescribers must counsel patients and their caregivers on how to recognize and respond to signs and symptoms of CRS and neurologic toxicity, including ICANS, the need to report all symptoms suggestive of CRS and neurologic toxicity, including ICANS to their healthcare

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provider or emergency room provider immediately, and the need to carry the **Patient Wallet Card** at all times.

- Prescribers must complete the **Patient Wallet Card** and provide the **Patient Wallet Card** to the patient or caregiver before treatment initiation (first step-up dose).

Indication

LYNOZYFIC is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Adverse Event Reporting

Healthcare providers must report serious adverse events of CRS and neurologic toxicity, including ICANS to the LYNOZYFIC REMS at 1-855-212-6391.

Healthcare providers should also report all other suspected adverse events associated with LYNOZYFIC to Regeneron Pharmaceuticals, Inc. at 1-844-734-6643 or medical.information@regeneron.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For a complete safety profile of LYNOZYFIC, please see the Prescribing Information included. For additional details about the REMS, please visit **www.Lynozyficrems.com** or contact the LYNOZYFIC REMS Coordinating Center at 1-855-212-6391.

Sincerely,

Regeneron Pharmaceuticals, Inc.

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