TECVAYLI™ REMS FACT SHEET

FDA - REQUIRED REMS SAFETY INFORMATION

TECVAYLI REMS Overview

- The **TECVAYLI** Risk Evaluation and Mitigation Strategy (REMS) is a safety program that manages the risks of Cytokine Release Syndrome (CRS) and Neurologic Toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). The **TECVAYLI** REMS is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.
- Prescribers, pharmacies and healthcare settings that prescribe and/or dispense **TECVAYLI** must be specially certified and trained on how to manage the risks of CRS and neurologic toxicity, including ICANS.
- Patients or their caregivers must receive the ***Patient Wallet Card*** before treatment initiation (first dose).
- Wholesalers and distributors must ONLY distribute **TECVAYLI** to certified pharmacies and healthcare settings.

What Are the Risks?

- CRS, including fatal or life-threatening reactions, may occur in patients receiving **TECVAYLI**. Initiate treatment with **TECVAYLI** step-up dosing schedule to reduce risk of CRS.
- Serious or life-threatening neurologic toxicity, including ICANS, may occur following treatment with **TECVAYLI**. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment.
- Withhold **TECVAYLI** until CRS or neurologic toxicity, including ICANS, resolves or permanently discontinue based on severity.

How Can Healthcare Providers Manage the Risks?

- Follow the **TECVAYLI** step-up dosing schedule as outlined in the ***Prescriber Training Program***.
- Administer pretreatment medications 1 to 3 hours before each dose of **TECVAYLI** to reduce the risk of CRS as outlined in the ***Prescriber Training Program***.
- Complete and provide patients or their caregivers with the ***Patient Wallet Card*** prior to treatment initiation (first dose).
- Instruct patients that they should stay at a healthcare setting for monitoring of signs and symptoms of CRS for 48 hours after administration of all doses within the step-up dosing schedule, including the first treatment dose.
- At the first sign of CRS, immediately evaluate the patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue **TECVAYLI** based on severity.
- Counsel patients to seek medical attention should signs or symptoms of neurologic toxicity occur.
- Monitor patients for signs or symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue **TECVAYLI** based on severity per recommendations and consider further management per current practice guidelines.
- For further details on recommended actions taken and treatment guidance for CRS and neurologic toxicity, including ICANS, refer to the ***Prescriber Training Program*** and ***Adverse Reaction Management Guide***.

TECVAYLI™ REMS FACT SHEET

Key Requirements of the TECVAYLI REMS

Healthcare providers that prescribe TECVAYLI

Receive training on the REMS requirements at www.TECVAYLIREMS.com using the ***Prescriber Training Program*** and the ***Adverse Reaction Management Guide***.

Successfully complete the ***Knowledge Assessment*** online.

Enroll in the REMS by completing the ***Prescriber Enrollment Form*** online and submit it to the REMS.

Fax and email options are also available.

If **TECVAYLI** will be dispensed and administered in the same location, an Authorized Representative must complete the Pharmacy and Healthcare Setting certification.

Counsel patients that they should be hospitalized and monitored for signs and symptoms of CRS and neurologic toxicity, including ICANS, for 48 hours after administration of all doses within the **TECVAYLI** step-up dosing schedule.

Pharmacies and Healthcare Settings that dispense TECVAYLI

Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS requirements.

NOTE: Certified **TECVAYLI** Prescribers cannot be designated as an Authorized Representative for a certified Pharmacy or Healthcare Setting.

Authorized Representative must be trained at www.TECVAYLIREMS.com using the ***Pharmacy and Healthcare Setting Training Program.***

Authorized Representative must enroll the Pharmacy/Healthcare Setting in the REMS by completing the ***Pharmacy and Healthcare Setting Enrollment Form*** online and submit it to the REMS Program. Fax and email options are also available.

Pharmacies and Healthcare Settings must verify prescriber certification in the **TECVAYLI** REMS before dispensing **TECVAYLI**.

Patients

Receive the ***Patient Wallet Card*** before treatment.

Should stay at a healthcare setting for monitoring of signs and symptoms of CRS and neurologic toxicity, including ICANS, for 48 hours after administration of all doses within the **TECVAYLI** step-up dosing schedule.

Wholesaler-Distributors

Establish processes and procedures to ensure that **TECVAYLI** is distributed only to certified pharmacies and healthcare settings.

Train all relevant staff involved in distribution on the **TECVAYLI** REMS requirements.

Maintain records of **TECVAYLI** distribution and provide these records to the REMS Program at least monthly.

Adverse Event Reporting

Healthcare providers must report serious adverse events suggestive of CRS and neurologic toxicity, including ICANS, to Janssen Biotech, Inc. at 1-800-Janssen (1-800-526-7736) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information, to enroll in the **TECVAYLI** REMS, and for all REMS materials go to www.TECVAYLIREMS.com

TECVAYLI™
(teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

For more information and to enroll in the TECVAYLI REMS, go to www.TECVAYLIREMS.com