

FDA-REQUIRED REMS SAFETY INFORMATION

The **TECVAYLI® REMS** is now called the **TECVAYLI® and TALVEY™ REMS**.

- For Prescribers certified in the **TECVAYLI REMS**, certification will automatically be transferred to the **TECVAYLI and TALVEY REMS**. Prescribers must review each product's USPI, **Adverse Reaction Management Guide** and the **Prescriber Training Program**.
- Risk of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) with **TECVAYLI** and **TALVEY**

Dear Healthcare Provider:

The **TECVAYLI REMS** has been replaced by the **TECVAYLI and TALVEY REMS**.

- As a prescriber previously certified in the **TECVAYLI REMS**, your certification will be automatically transferred to the **TECVAYLI and TALVEY REMS** and you will be able to prescribe both **TECVAYLI** and **TALVEY**.
- Prescribers must review each product's USPI, the **Adverse Reaction Management Guide**, and the **Prescriber Training Program**.

Serious Risks of **TECVAYLI** and **TALVEY**

- **Cytokine release syndrome (CRS)**, including life-threatening or fatal reactions, can occur in patients receiving **TECVAYLI** or **TALVEY**.
 - Initiate treatment with **TECVAYLI** or **TALVEY** step-up dosing schedule to reduce the risk of CRS.
- **Neurologic toxicity, including ICANS** and serious and life-threatening or fatal reactions, can occur in patients receiving **TECVAYLI** or **TALVEY**.
 - Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment.
- Withhold **TECVAYLI** or **TALVEY** until CRS or neurologic toxicity, including ICANS, resolves or permanently discontinue based on severity per recommendations and consider further management per current practice guidelines.

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

REMS Requirements

- Those who prescribe and/or dispense **TECVAYLI** and/or **TALVEY** must be aware of how to manage the risks of CRS and neurologic toxicity, including ICANS.
- **TECVAYLI** and **TALVEY** are ONLY prescribed and/or dispensed by certified prescribers, pharmacies and healthcare settings.

- Prescribers must counsel patients on signs and symptoms of CRS and neurologic toxicity, including ICANS, using the **Patient Wallet Card**.
- Complete the **Patient Wallet Card** for the patient or caregiver and provide it to him/her.

Indications

TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed and CD3-directed 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.

TALVEY is a bispecific GPRC5D-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 any 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.

Healthcare providers should report all suspected adverse events or product quality complaints to Janssen at 1-800-Janssen (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

For complete safety profiles of **TECVAYLI** and **TALVEY**, please see the Prescribing Information included. For additional details about the REMS, please visit www.TEC-TALREMS.com or contact the **TECVAYLI and TALVEY REMS** Coordinating Center at 1-855-810-8064. Please note that **TECVAYLIREMS.com** and **TALVEYREMS.com** will redirect to www.TEC-TALREMS.com.

Sincerely,

Janssen Biotech, Inc.