Seagen®

Genmab

IMPORTANT DRUG WARNING

June 2023

Important Drug Warning

Subject: **Severe Cutaneous Adverse Reactions, Including Stevens-Johnson Syndrome, Reported with TIVDAK® (tisotumab vedotin-tftv)**

Dear Healthcare Provider,

This letter is to inform you of new safety information for TIVDAK, indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Seagen is in discussions with FDA to update the USPI for TIVDAK.

Summary:

- Severe cutaneous adverse reactions, including events of fatal or life-threatening Stevens-Johnson syndrome (SJS), have been reported in patients treated with TIVDAK.
- A cumulative analysis across all safety data sources inclusive of clinical trial and post-marketing data as of 24 May 2023 identified two patients treated with TIVDAK who had severe cutaneous adverse reactions that were considered serious. Both cases were reported as SJS, one of which had a fatal outcome.

Recommendations to the Healthcare Provider:

- Inform patients that severe cutaneous adverse reactions, including SJS, have been reported after administration of TIVDAK.
- Instruct patients to contact their healthcare provider to seek immediate medical attention for signs and symptoms of severe cutaneous adverse reactions.
- Monitor patients for signs and symptoms of severe cutaneous adverse reactions.
- Withhold TIVDAK for suspected severe cutaneous adverse reactions until the etiology of the reaction has been determined.
- Consult a specialist to confirm diagnosis of severe cutaneous adverse reactions, including SJS, and guide appropriate management.
- Permanently discontinue TIVDAK for confirmed Grade 3 or 4 severe cutaneous adverse reactions, including SJS.

Additional Information on Safety Concern

As of 24 May 2023, two patients treated with TIVDAK had severe cutaneous adverse reactions that were considered serious, one of whom had a fatal outcome. Both cases were reported as SJS from the ongoing, confirmatory, global, innovaTV 301/ENGOT cx-12/GOG 3057 trial.

The two patients had stage IVB cervical cancer. Both presented with progressive symptoms of SJS (e.g., blistering, peeling, skin detachment) shortly after the first or second dose of tisotumab vedotin, which led to hospitalization and diagnosis.

This letter is not intended to provide a complete description of the benefits and risks related to the use of TIVDAK. Please refer to the full **Prescribing Information enclosed, as well as the Medication Guide**. Seagen is in discussions with FDA to update the USPI for TIVDAK.

Reporting Adverse Events

Healthcare providers and patients are encouraged to report adverse events in patients taking TIVDAK to Seagen Inc. at 1-855-473-2436 (**drug.safety@seagen.com**) or to the FDA at 1-800-FDA-1088 (**www.fda.gov/medwatch**).

Company Contact Point

You may also contact our medical information department at 1-855-473-2436 or **medinfo@seagen.com** if you have any questions about the information contained in this letter or the safe and effective use of TIVDAK.

Sincerely,

Karin A Tollefson

Karin A. Tollefson, PharmD
Sr Vice President, Global Medical Affairs
Seagen Inc.

Yasir Nagarwala, MD
Sr Vice President, Global Medical Affairs
Genmab US, Inc.