Trodelvy® (sacituzumab govitecan-hziy) Vesicant/Irritant Properties and Extravasation

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) use as monotherapy and the vesicant/irritant properties and extravasation.

Gilead continually assesses safety data from all sources for unidentified drug reactions and updates the product label information accordingly to reflect the safety profile of SG. Because case reports of potential adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish causal relationship to drug exposure. For this reason, Gilead does not provide information from post-marketing spontaneous reports.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings for neutropenia and diarrhea are available at: www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.

Relevant Product Labeling[1]

Dosage and Administration

Recommended dosage

The recommended dosage of SG as a single agent or in combination with pembrolizumab is 10 mg/kg administered as an IV infusion on Days 1 and 8 of each 21-day cycle. Continue SG until disease progression or unacceptable toxicity. Do not administer SG at doses >10 mg/kg.

Preparation and administration

Reconstitution

SG is a hazardous drug. Follow applicable special handling and disposal procedures.

Administration

Administer SG as an IV infusion.

- First infusion: Administer over 3 hours. Observe patients during the infusion and for at least 30 minutes following the initial dose, for signs or symptoms of infusion-related reactions.

- Second and subsequent infusions: Administer over 1 to 2 hours if prior infusions were tolerated. Observe patients during the infusion and for at least 30 minutes after infusion.

Description

SG is a Trop-2 directed antibody and topoisomerase inhibitor conjugate, composed of the following three components:

- the humanized monoclonal antibody, hRS7 IgG1κ (also called sacituzumab), which binds to Trop-2 (the trophoblast cell-surface antigen-2);
- the drug SN-38, a topoisomerase inhibitor;
- a hydrolysable linker (called CL2A), which links the humanized monoclonal antibody to SN-38.

Vesicant/Irritant Properties of SG[1]

SG is not classified as a vesicant/irritant in the SG US FDA-approved Prescribing Information.

Management of SG Infiltration/Extravasation

There are no recommendations regarding management of infiltration/extravasation in the SG US FDA-approved Prescribing Information.[1]

Gilead is unable to provide treatment or patient management recommendations. For the management of infiltration/extravasation please refer to your institutional guidelines or to the treating physician. Clinical judgement/discretion of the treating healthcare professional should be used when determining the optimal treatment approach for each individual patient.

Reference

1. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Trodelvy US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.

Follow-Up

For any additional questions, please contact Trodelvy Medical Information at:

☎ 1-888-983-4668 or www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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