GILEAD | Medical Information

# Trodelvy® (sacituzumab govitecan-hziy) Concentration After Reconstitution

This document is in response to your request for information regarding the concentration after the reconstitution of Trodelvy® (sacituzumab govitecan-hziy [SG]).

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

#### Preparation and administration

***Reconstitution***

- SG is a hazardous drug.
- Follow applicable special handling and disposal procedures.
- Calculate the required dose (mg) of SG based on the patient's current body weight.
- Using a sterile syringe, slowly inject 20 mL of 0.9% sodium chloride injection, USP, into each 180 mg SG vial. Each vial contains overfill to compensate for liquid loss during preparation and after reconstitution, the total resulting volume delivers a concentration of 10 mg/mL.
- Gently swirl vials and allow to dissolve for up to 15 minutes. Do not shake. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution should be free of visible particulates, clear and yellow. Do not use the reconstituted solution if it is cloudy or discolored.
- Use immediately to prepare a diluted SG infusion solution.

## Additional Data on SG Concentration After Reconstitution

A review of the data on file revealed the following additional information:

- The target fill amount of drug product is 200 mg per SG vial. The amount of drug indicated on the US FDA-approved prescribing information (180 mg/vial) represents the minimum amount of drug possibly contained in the vial based on filling and extraction variability.[2]

- Based on the target fill amount of 200 mg per vial,[2] upon reconstitution with 20 mL of 0.9% sodium chloride injection, USP, following instructions contained in the US FDA-approved prescribing information, the resulting target concentration is 10 mg/mL.[1]

## References

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

## 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 🖱 https://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

## Data Privacy

The Medical Information service at Gilead Sciences may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers, and regulatory authorities located in countries other than your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact privacy@gilead.com.