

# Trodelvy® (sacituzumab govitecan-hziy) Monotherapy: Alternative Dosing and Dosing Schedules

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and alternative dosing and dosing schedules.

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:

https://www.gilead.com/-

/media/files/pdfs/medicines/oncology/trodelvy/trodelvy\_pi.pdf

# Relevant Product Labeling<sup>1</sup>

### **Dosage and Administration**

### Recommended Dosage

The recommended dosage of SG is 10 mg/kg administered as an IV infusion once weekly on Days 1 and 8 of 21-day treatment cycles. Continue treatment until disease progression or unacceptable toxicity. Do not administer SG at doses >10 mg/kg.

# **Alternative Dosing and Dosing Schedules**

A literature search was conducted in Ovid MEDLINE, BIOSIS Previews, and Embase databases for studies published between 1946 and 7 March 2025, using search terms of sacituzumab govitecan, alternative dosing, alternative dosing schedule, dosing schedule, and related terms. No case reports or clinical studies examining the efficacy and safety outcomes associated with alternative dosing or schedules for SG monotherapy were identified. This includes studies using alternative dosing or schedules for patients who are overweight or underweight, to mitigate adverse events, or to align with the dosing of granulocyte-colony stimulating factor (G-CSF).

### References

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: <a href="https://www.gilead.com/-">https://www.gilead.com/-</a>/media/files/pdfs/medicines/oncology/trodelvy/trodelvy\_pi.pdf.

# Follow Up

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

21-888-983-4668 or 4 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

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