

What to expect while participating in the TROPHY-U-01 trial

Thank you for considering taking part in the TROPHY-U-01 trial. If you meet trial requirements and are enrolled, you will be given standard treatment for mUC, the study drug, or a combination of both.

Purpose of study



The purpose of the study is to find out if the study drug, sacituzumab govitecan, is safe and effective when taken alone or when combined with other standard treatments.



STUDY CALENDAR EXAMPLE*

		Treatment		Follow-up		
	Screening	Cycles 1-6		Treatment	Safety	Long-term
	28 days before first dose of study drug	Day 1	Day 8	Within 4 weeks after stopping study drug	30 days after stopping study drug	Every 12 weeks after stopping study drug (max 2 years)
Infusion dates		✓	✓			
Physical exam/labs	✓	✓		✓	✓	
Side effect reporting		✓	✓			
Televisit						✓

Imaging scans (CT/MRI): every 6 weeks up to Cycle 12, then every 9 weeks.

*Your personal study calendar may differ. Please see the Informed Consent document you received for more detailed information.

BEFORE TREATMENT



Time: Up to 28 days before first treatment

You will need to visit the clinic for:

- Physical exam and vitals
- CT/MRI
- ECG
- Bloodwork and urine samples
- Tumor biopsy (tissue samples) might be needed if your tumor sample is not already available

DURING TREATMENT



Time: 6 months, or longer if your study doctor believes there is benefit to you continuing study treatment

This is summarized in the study calendar on reverse side. Study treatment will be given by intravenous infusion (injected into a vein) in **3-week cycles**.

You will need to visit the clinic twice per cycle for infusions on Days 1 and 8.

- **Day 1:** Before your infusion, you will complete a physical exam and bloodwork. This allows the team to monitor how you are responding to treatment
- **Day 8:** Infusion

Prior to treatment: Before infusion of the study treatment, you will be given medication to reduce the chance of side effects.

Side effects: The most common side effects of the study drug include decreased blood cell counts, diarrhea, nausea, and vomiting. These are not all possible side effects. Rare but serious side effects can happen. Make sure to report any and all side effects to the study team.

Time: Tests and procedures on infusion days can take up to 8 hours.

END OF STUDY TREATMENT



Time: within 4 weeks of last dose

You will have to visit the clinic for a physical exam, vitals, bloodwork, and possible scans.

LONG-TERM FOLLOW-UP



Time: maximum 2 years

You will have 1 call or visit every 3 months for a maximum of 2 years for information on your overall health status.

FAQs

How much will treatment cost?

Study drug, study visits, and lab tests or procedures that are a part of this study will be provided at no cost to you. You or your health care payer are responsible for any other health care costs. Talk with the study team or review the Informed Consent document to find out what is covered.

Will I be compensated for participating in this study?

You will not receive payment for taking part in the study. However, you may be eligible to receive reimbursement for your travel expenses.

These materials are intended to be shared by health care professionals involved in the TROPHY-U-01 study with mUC patients who might be eligible for enrollment.

If you have any other questions, please contact your local study team:

