Sacituzumab govitecan-hziy (Trodelvy™)

Pronounced: SAK-I-TOOZ-ue-mab GOE-vi-TEE-kan

Classification: Trop-2-directed antibody and topoisomerase inhibitor conjugate

About Sacituzumab govitecan-hziy (Trodelvy™)

Sacituzumab govitecan-hziy is an antibody-drug conjugate (an antibody with a cell-killing medication attached to it) directed against a protein called Trop-2 (trophoblast cell surface antigen 2), found on the surface of some cancer cells. Antibodies, which are normally found in the body, are developed by the immune system to destroy foreign material (such as a germ). Sacituzumab govitecan-hziy is a manmade antibody that causes the immune system to attack cancer cells that have the Trop-2 protein on them. Along with this antibody, sacituzumab govitecan-hziy has a medication attached to it called a topoisomerase I inhibitor. Topoisomerase inhibitors work against certain enzymes, called topoisomerase I, to stop cancer cells from replicating their DNA, which leads to cell death.

How to Take Sacituzumab Govitecan-hziy

Sacituzumab govitecan-hziy is given by IV (into a vein) infusion. The dose is based on your weight, and how often you receive the medication will be decided by your care team.

Prior to each dose, you will be given acetaminophen, diphenhydramine, a histamine-2 antagonist like famotidine, and possibly a corticosteroid to prevent any reactions. You will also be given medications to prevent nausea and vomiting. Let your nurse or provider know right away if you feel any different during the infusion, and are experiencing things like chills, fever, nausea, shortness of breath, itching, flushing, swelling of face, lip, or tongue, or tightness in your chest or throat.

Before receiving Sacituzumab govitecan-hziy, tell your provider if you have ever been told that you carry a genetic mutation of the uridine diphosphate-glucuronosyl transferase (UGT1A1) gene, such as homozygosity for the UGT1A1*28 allele. This can put you more at risk for certain side effects.

The blood levels of this medication can be affected by certain medications, so they should be avoided. These include carbamazepine, phenytoin, phenobarbital, rifampin, efavirenz, among others. Be sure to tell your healthcare provider about all medications and supplements you take.

Possible Side Effects

There are a number of things you can do to manage the side effect of Sacituzumab govitecan-hziy. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips for preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
Avoid large crowds and people who are sick (i.e.: those who have a cold, fever, or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

**Diarrhea**

Diarrhea can be a serious side effect of sacituzumab govitecan-hziy. It can lead to severe dehydration. Diarrhea can be defined as an increase in the number of bowel movements you have in a day. Your healthcare provider will tell you how to take loperamide (an anti-diarrheal medication) at home, which you should start taking as soon as diarrhea starts. If your provider has not told you to take an anti-diarrheal at home, make sure to call your provider the first episode of diarrhea that you have.

Runny nose, excess saliva, watery eyes, sweating, and cramping can accompany diarrhea that happens within the first day of receiving this medication. If any of these symptoms occur during the infusion, notify your nurse. Your healthcare team may administer a medication in the clinic if you develop diarrhea right away.

**Nausea and/or Vomiting**

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy, or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Fatigue**

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Liver Toxicity**

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

**Low Red Blood Cell Count (Anemia)**

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Loss or Thinning of Scalp and Body Hair (Alopecia)**

Your hair may become thin, brittle, or may fall out. This typically begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats, and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you
warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

**Infusion-Related Side Effects**

The infusion can cause a reaction that may lead to chills, fever, low blood pressure, nausea, and vomiting. You will receive acetaminophen and diphenhydramine prior to the infusion to help prevent these reactions. Some patients will also receive a steroid before the infusion to prevent a reaction. Reactions are most common during the first week of therapy, including the evening after the infusion. Your oncology care team will tell you what to do if this happens.

**Constipation**

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

**Rash**

Some patients may develop a rash, scaly skin, or red itchy bumps. Use an alcohol-free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your oncology care team can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your oncology care team of any rash that develops, as this can be a reaction. They can give you more tips on caring for your skin.

**Low Platelet Count (Thrombocytopenia)**

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib) etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding the use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

**Decrease in Appetite**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

**Aches and Headache**
Sacituzumab Govitecan-hziy can cause back pain, abdominal pain, and headaches, which can interfere with quality of life. Your healthcare provider can recommend medications and other strategies to help relieve pain.

**High Blood Sugar**

This medication can cause elevated blood sugar levels in patients with and without diabetes. Your oncology care team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the healthcare team.

**Peripheral Neuropathy (Numbness or Tingling in the Hands and/or Feet)**

Peripheral neuropathy is a toxicity that affects the nerves. It causes numbness or a tingling feeling in the hands and/or feet, often in the pattern of a stocking or glove. This can get progressively worse with additional doses of the medication. In some people, the symptoms slowly resolve after the medication is stopped, but for some, it never goes away completely. You should let your oncology care team know if you experience numbness or tingling in the hands and/or feet, as they may need to adjust the doses of your medication.

**Dizziness**

This medication can cause dizziness. Tell your provider if you are having dizziness, especially if it is interfering with your daily life.

**Electrolyte Abnormalities**

This medication can affect the normal levels of electrolytes (potassium, magnesium, calcium, etc.) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

**Sexual & Reproductive Concerns**

This medication may affect your reproductive system and fertility. Talk with your provider about any concerns you might have if you wish to have children in the future.

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. For women, effective birth control is necessary during treatment and for at least 6 months after treatment, even if your menstrual cycle stops. For men, effective birth control is necessary during treatment and for at least 3 months after treatment, even if you believe you are not producing sperm. You should not breastfeed while receiving this medication and for 1 month after the last dose.