

PATIENT INFORMATION
TREGZI™ (treg-zee)
(allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq)

What is TREGZI?

- TREGZI is a treatment used in stem cell transplant for adult patients who have blood cancer to rebuild the blood and immune systems and improve survival without chronic graft-versus-host disease (cGVHD).
- TREGZI is made by selecting certain types of blood cells from a matched donor.

Before you receive TREGZI, tell your healthcare provider about all your medical conditions, including if you have:

- Lung or breathing problems
- Heart problems
- Liver problems
- Kidney problems
- A recent or active infection

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive TREGZI?

- TREGZI is made from the blood cells of a matched donor who may or may not be related to you. The donor's cells will be collected by a process called apheresis.
- The donor's blood is sent to a manufacturing center to make TREGZI. It takes about 72 hours from the time the donor's blood is collected to when you will receive the first infusion bag of TREGZI.

Before you get TREGZI, your healthcare provider will give you chemotherapy and/or radiation to prepare your body.

Thirty minutes before you are given TREGZI, you may be given other medicines. These may include:

- Medicine for an allergic reaction (such as diphenhydramine)
- Medicine for fever (such as acetaminophen)

Your healthcare provider will give TREGZI to you through a catheter (tube) placed into your vein (intravenous infusion). Your TREGZI will be given as 3 separate infusion bags over 2 or 3 days. Two infusion bags will be given on the first infusion day. The third infusion bag will be given 2 or 3 days after.

What are the possible side effects of TREGZI?

TREGZI can cause serious side effects, including:

- **Graft Failure.** Failure to rebuild the blood and/or immune system, which may be fatal, can occur after receiving TREGZI. Your healthcare provider will monitor you closely after TREGZI administration.
- **Graft-Versus-Host Disease (GVHD).** Immune reactions from the donor's cells may occur soon (days) or long (months) after receiving TREGZI. Tell your healthcare provider right away about any signs and symptoms including rash, joint pain, diarrhea, or yellowing of the eyes.
- **Infusion Reactions.** Infusion reactions can occur after TREGZI infusion. Tell your healthcare provider right away about any signs and symptoms including fever, chills, flushing, fatigue, shortness of breath, and dizziness/lightheadedness.
- **Secondary Cancer and Cancer from Donor Cells.** New cancers can develop after treatment with TREGZI. If you are diagnosed with a new cancer after treatment, contact Orca Bio at 1-877-411-6722.

- **Transfer of Serious Infections.** Transfer of serious infectious diseases can occur because TREGZI is made from the human blood cells of a donor. Transfer may occur even though donors are screened and tested for infectious diseases.

The most common side effects of TREGZI include:

- Inflammation of the digestive tract
- rash
- infections from an unknown pathogen
- vomiting
- bacterial infections
- acute graft-versus-host disease (aGVHD)
- fungal infections
- diarrhea
- viral infections
- abdominal pain
- nausea
- bleeding
- swelling

These are not all the possible side effects of TREGZI. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call [1-800-FDA-1088](tel:1-800-FDA-1088).

General information about the safe and effective use of TREGZI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more information about TREGZI, talk with your healthcare provider.

You can ask your healthcare provider for information about TREGZI that is written for health professionals. For more information on TREGZI, go to www.TREGZI.com or call 1-800-290-6722.

What are the ingredients in TREGZI?

Active ingredients: hematopoietic stem and progenitor cells (HSPCs), convention T cells (Tcons), and regulatory T cells (Tregs)

Inactive ingredients: dimethyl sulfoxide (DMSO), hetastarch, human serum albumin (HSA), multiple electrolytes injection (MEI), and sodium chloride injection

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