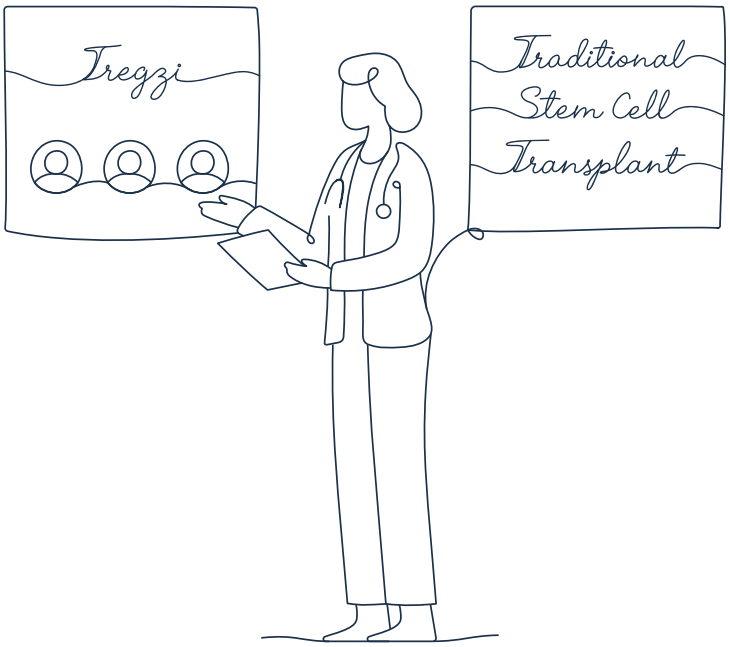


INFO ABOUT TREGZI

For people living with blood cancers,

Discover what's possible with TREGZI:

The first and only precision-engineered stem cell and T cell therapy for allogeneic transplant

INDICATION AND IMPORTANT SAFETY INFORMATION

- 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.

Please see additional Important Safety Information throughout.

TREGZI®
(allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq) Suspension For IV infusion

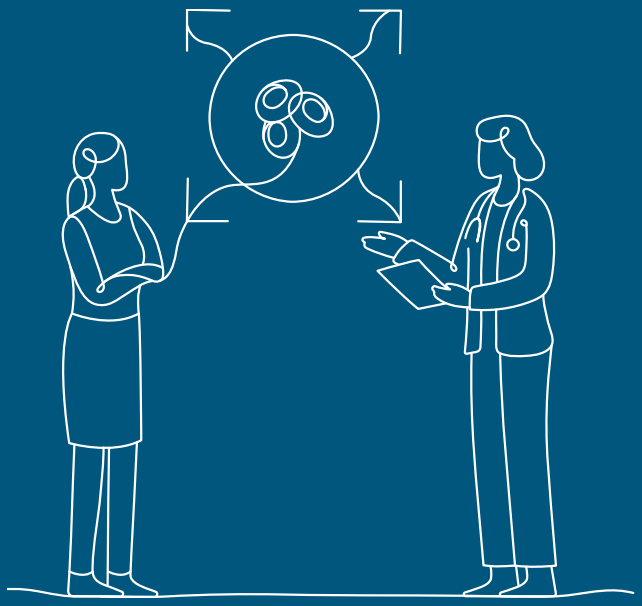
TREGZI is a unique type of stem cell and T cell therapy for allogeneic transplant that is different than traditional allogeneic stem cell transplant approaches.

It's been shown to improve survival without chronic graft-versus-host disease (also called cGVHD) in adults with blood cancers.

TREGZI contains a defined set of 3 types of cells (combination of stem cells and T cells) working together to rebuild your blood and immune system and its ability to target the cancer:

- The donor stem cells contained in TREGZI grow and divide into the healthy blood and immune cells your body needs
- The donor T cells in TREGZI help your body fight the cancer while reducing the potential for GVHD

Each of the different types of cells in TREGZI is delivered into your body at a set time. This allows your immune system to rebuild and reduces the risk of complications such as GVHD.



Important Safety Information (cont'd)

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.

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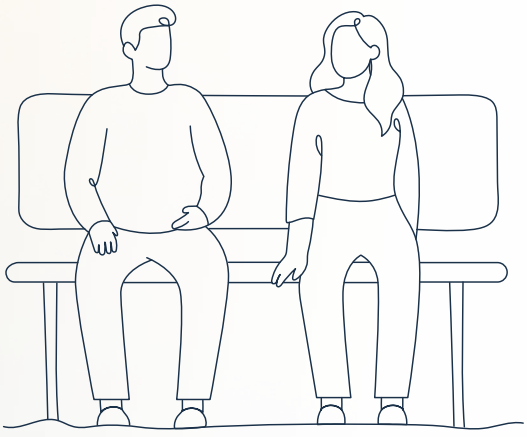
About TREGZI

Differences between TREGZI and traditional stem cell transplant

Key characteristics	TREGZI	Traditional stem cell transplant
Potentially curative for certain blood cancers	x	x
Can be given early in the treatment journey or after having tried other therapies	x	x
Replaces damaged blood cells and the immune system with new health cells	x	x
Uses cells from a donor	x	x
Transplants stem cells and other cells found in the donor's blood at one time		x
Transplants donor stem cells in a set order	x	
Made of purified sets of donor HSPCs, Tregs, and Tcons	x	

HSPC, hematopoietic stem and progenitor cell; Tcon, conventional T cell; Treg, regulatory T cell.



Important Safety Information (cont'd)

TREGZI can cause serious side effects, including:

- **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 1-877-290-6722.
- **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

Please see additional Important Safety Information throughout.

TREGZI gave people a greater chance of survival without moderate-to-severe cGVHD

About the Precision-T trial

Precision-T was a multicenter phase 3 randomized trial that included people with acute lymphoblastic leukemia (ALL), acute myeloid leukemia (AML), and myelodysplastic syndromes (MDS). People were randomized into 2 groups, where they received either TREGZI + tacrolimus (a chemotherapy-free immunosuppressant) or traditional stem cell transplant + tacrolimus and methotrexate (a chemotherapy). Ninety-three people were in the TREGZI group, and 94 people were in the traditional stem cell transplant group. The main goal of the study was to assess survival free from moderate or severe cGVHD, also called cGFS.

Treatment Results

~2x greater

chance of survival free of moderate-to-severe cGVHD (cGFs)

78% of people who received TREGZI + tacrolimus were alive and free of cGVHD at 1 year after transplant compared with **38.4%** of people who received traditional allogeneic stem cell transplant + tacrolimus and methotrexate

~3.5x lower

risk of developing moderate-to-severe cGVHD

Just **12.6%** of people who received TREGZI + tacrolimus developed cGVHD compared with **44%** of people who received traditional stem cell transplant + tacrolimus and methotrexate at 1 year after transplant

At 1 year, **about 94% of people who received TREGZI + tacrolimus were alive** compared with about 83% of those who received traditional allogeneic stem cell transplant + tacrolimus and methotrexate. The difference between the 2 treatment groups was not statistically meaningful.

Survival results are descriptive only and cannot be interpreted as definitive evidence

Please see additional Important Safety Information throughout.

Safety

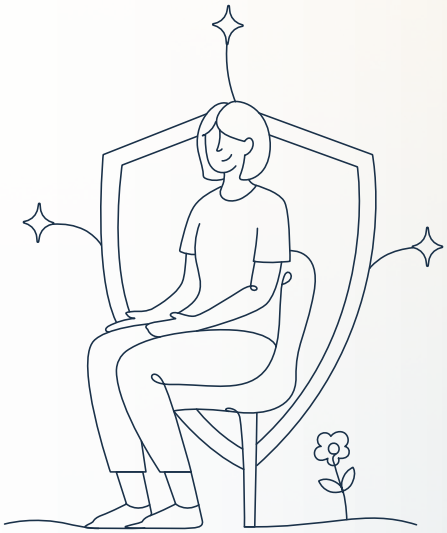
Possible side effects

Although TREGZI has been designed to help lower the risk of certain complications, they may still occur. Because everyone responds differently to treatment, it is not possible to know whether you will experience any adverse effects or how severe they may be.

Side effects seen in ≥20% of people who received TREGZI in the clinical trial were:

- Inflammation of the digestive tract
- Diarrhea
- Rash
- Viral infections
- Infections from an unknown pathogen
- Abdominal pain
- Vomiting
- Nausea
- Bacterial infections
- Bleeding
- Acute GVHD
- Swelling
- Fungal infections

These are not all the possible side effects of TREGZI.



Visit TREGZI.com to learn more.

Important Safety Information (cont'd)

The most common side effects of TREGZI include inflammation of the digestive tract, diarrhea, rash, viral infections, infections from an unknown pathogen, abdominal pain, vomiting, nausea, bacterial infections, bleeding, acute graft-versus-host disease (aGVHD), swelling and fungal infections.

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.

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IMPORTANT SAFETY INFORMATION AND INDICATION

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Please see full Prescribing Information including Patient Information.

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