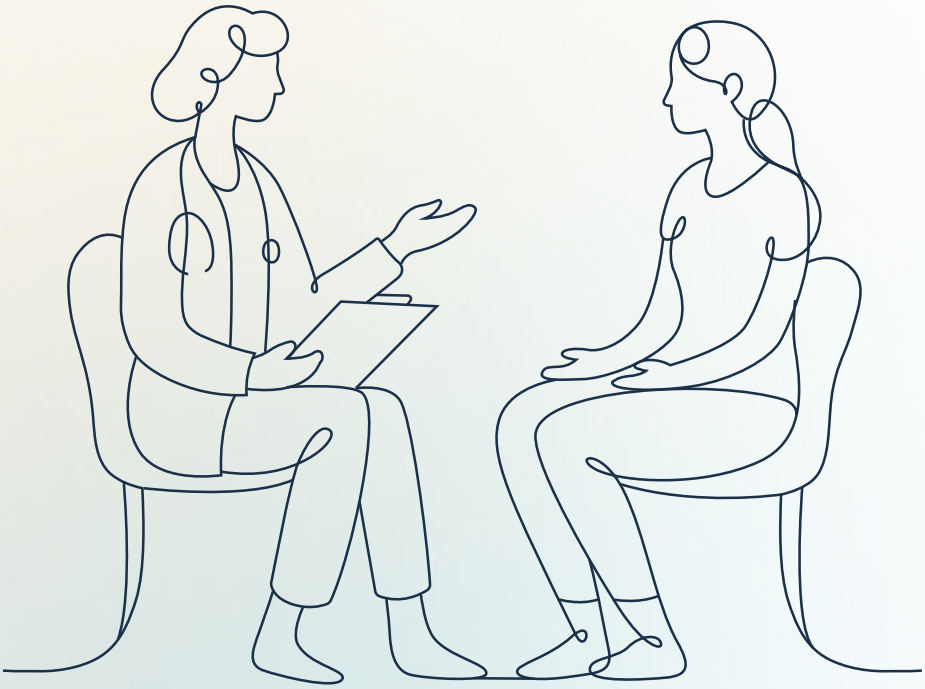
TREGZI™
(allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq) Suspension For IV infusion

FAQ



Frequently Asked Questions About TREGZI

The following answers to frequently asked questions can help you learn about TREGZI, the first and only precision-engineered stem cell and T cell therapy for allogeneic transplant in adults with blood cancers, and what you could expect from treatment.

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.

What to know about TREGZI

To best understand what TREGZI is, it will help to understand how it differs from traditional allogeneic stem cell transplant approaches.

TREGZI is a unique type of stem cell and T cell therapy for allogeneic transplant that has been shown to improve survival without chronic graft-versus-host disease (also called cGVHD) in adults with blood cancers.

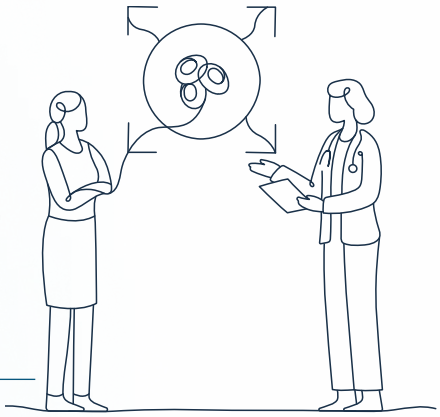
On the pages that follow, you'll find answers to commonly asked questions about TREGZI that can help you learn more about treatment. The information presented here is not intended to replace a discussion with your healthcare team. If you have questions about treatment with TREGZI and whether it could be right for you, please talk with your healthcare team.

What is TREGZI?

TREGZI is a precisely designed therapy for transplant that contains both donor (allogeneic) stem cells and T cells.

- The donor stem cells contained in TREGZI are meant to grow and divide into the healthy blood and immune cells your body needs
- The T cells in TREGZI help rebuild your immune system so that it is better able to fight the cancer, while reducing the risk of cGVHD

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



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.

Please see additional Important Safety Information throughout.

How is TREGZI different from traditional allogeneic stem cell transplant?

Both TREGZI and traditional allogeneic stem cell transplant replace cancer cells with healthy ones and offer the chance for a cure. Yet there are important differences with TREGZI that can impact the overall treatment experience.

TREGZI is a precisely designed allogeneic stem and T cell therapy that balances 2 different types of T cells. Each of the different types of cells in TREGZI is delivered into your body at a set time. This helps your blood and immune system to rebuild and can reduce the risk of complications such as cGVHD.

What types of cells are transplanted with TREGZI?

With TREGZI, stem cells and 2 types of T cells from a donor are transplanted.



Starter cells

These cells, called **hematopoietic stem and progenitor cells (HSPCs)**, are the cells that grow into the different types of blood cells your body needs, including red blood cells, white blood cells, and platelets.

The T cells include:

Suppressor cells

- **Regulatory T cells (Tregs)** lower (suppress) the powerful immune response started by the body's Tcons once the infected or cancerous cells have been eliminated. Tregs can also suppress harmful immune attacks caused by the donor cells against your body, which can help protect your tissues and lower the risk of complications, including cGVHD.

Fighter cells

- **Conventional T cells**, called **Tcons**, are your body's "fighter cells." They travel through your bloodstream, seeking out infected or cancerous cells. When they find them, Tcons recruit other immune cells and direct a robust response to eliminate them.

There is good reason why TREGZI balances 2 different types of T cells: Tcons send a "go" signal to the immune cells to defend you while Tregs sends a signal to "slow down" that protects you from an overactive immune system. A healthy immune system relies on a balance between signals to fight disease without harming the body itself.

Important Safety Information, cont'd

TREGZI can cause serious side effects, including: (cont'd)

- **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.

Please see additional Important Safety Information throughout.

About the Precision-T trial

Precision-T was a multicenter phase 3 randomized trial that included people with different types of blood cancer, such as 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 chronic GVHD (cGVHD), also called cGFS.

What kind of results could I expect with TREGZI?

In the clinical trial, Precision-T, TREGZI + tacrolimus was shown to give people a greater chance of survival without moderate-to-severe chronic GVHD (also called cGFS) and lower risk of severe infection compared with traditional allogeneic stem cell transplant + tacrolimus and methotrexate.

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

~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 allogeneic 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 people 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**

TREGZI lowered the risk of severe infection

~2.5x lower

risk of severe infection

- 8.4% of people who received TREGZI + tacrolimus developed severe infections at 1 year after transplant compared with 16.1% of people who received traditional allogeneic stem cell transplant + tacrolimus and methotrexate

Important Safety Information, cont'd

TREGZI can cause serious side effects, including: (cont'd)

- **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.

Please see additional Important Safety Information throughout.

Are there side effects with TREGZI?

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.

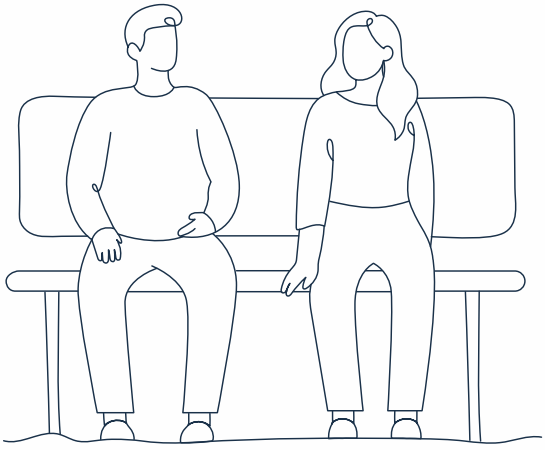
Important Safety Information, cont'd

TREGZI can cause serious side effects, including: (cont'd)

- **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, 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.



Please see additional Important Safety Information throughout.

What's involved with getting TREGZI?

There are a number of steps involved with TREGZI. The process includes:

Finding a suitable donor. The search for a donor may begin shortly after diagnosis. Once a healthy donor is found, the donor cells are collected and TREGZI is made for your transplant.

Preparing for your infusion. A few days before TREGZI is given, you will receive a course of chemotherapy and/or radiation, called a conditioning regimen. This is done to destroy as many of the cancer cells as possible and to purposefully weaken your immune system so that it accepts the new cells.

Getting your TREGZI. On the first day of transplant, you will receive the first 2 types of your carefully selected donor cells, the HSPCs and the Tregs. About 2 to 3 days later, you'll receive the third type of donor cells, the Tcons.

How long will I have to wait for my TREGZI from the time the donor cells are collected?

The goal is to administer your first TREGZI infusion bag within 72 hours or less from the time the cells were collected.

How long does it take for the new cells to start working?

Following transplant, the new cells will travel through your bloodstream to your bone marrow, where they will begin to make new cells. This is called engraftment. The first signs of engraftment will be an increase in the number of white blood cells and platelets circulating in your system. It takes about 2-4 weeks after transplant for this to happen.

Important Safety Information, cont'd

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What support is available for accessing TREGZI?

Orca Bio is here to support you and your caregiver with access to TREGZI and guidance throughout the treatment process.

Through **MyTREGZI Support**, you and your caregiver may receive help with*:

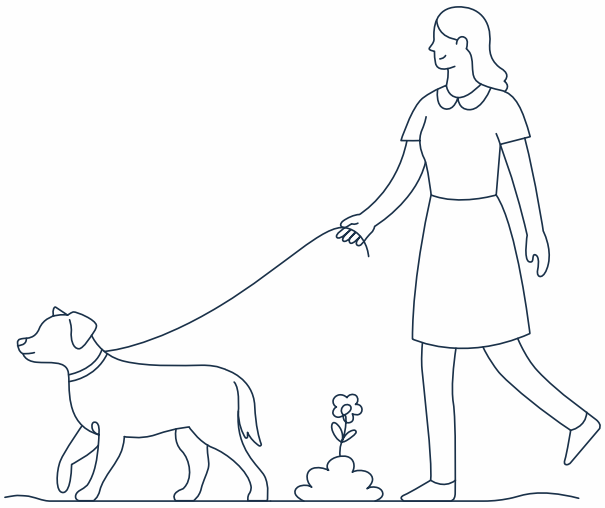
- Transportation
- Lodging
- Out-of-pocket costs for meals
- Other travel expenses related to treatment with TREGZI

*Financial and other eligibility requirements apply.

MyTREGZI Support

MyTREGZI Support specialists can be reached by calling:
1-877-411-ORCA (select option 4)
Monday through Friday,
8:00 AM to 8:00 PM Eastern Time

Scan to learn more about TREGZI



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Please see full Prescribing Information including Patient Information.

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