

## SECOND GENERATION TRAIL BLAZER

first generation  
to **DELAY HER T1D**

**FOR THE FIRST TIME EVER, IT'S POSSIBLE  
TO DELAY THE ONSET OF STAGE 3 T1D**

Actor portrayal

### What is TZIELD?

TZIELD is a prescription medicine used to delay the onset of Stage 3 type 1 diabetes, which is when your body can't make enough insulin on its own and may require insulin injections. TZIELD is for **adults and children 8 years of age and older who have Stage 2 type 1 diabetes**. This means they have tested positive for 2 or more type 1 diabetes-related autoantibodies, have abnormal blood sugar levels, and do not have type 2 diabetes. It is not known if TZIELD is safe and effective in children under 8 years of age.

### IMPORTANT SAFETY INFORMATION

#### What is the most important information I should know about TZIELD?

TZIELD may cause serious side effects, including:

- **Cytokine Release Syndrome (CRS)**. Signs and symptoms of CRS problems may include:
  - » fever
  - » feeling tired (fatigue)
  - » muscle and joint pain
  - » nausea
  - » headache
  - » increased liver enzymes in your blood

These signs and symptoms may start during the first 5 days of TZIELD treatment. Tell your healthcare provider right away if you develop any signs and symptoms of CRS during treatment with TZIELD.

Please see Important Safety Information throughout.

Please see [Medication Guide](#) and [Prescribing Information](#).





Actor portrayal

*Explore how*  
**TZIELD IS CHANGING  
THE WAY  
TYPE 1 DIABETES (T1D)  
IS TREATED**

**IMPORTANT SAFETY INFORMATION (CONT'D)**

What is the most important information I should know about TZIELD?

TZIELD may cause serious side effects, including:

- **Decrease in white blood cells.** TZIELD may cause a decrease in a type of white blood cell called lymphocytes. A decrease in white blood cells is a serious, but common side effect that can affect your body's ability to fight infections.

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UNDERSTANDING THE STAGES OF TYPE 1 DIABETES

WHAT IS TZIELD?

CLINICAL TRIAL RESULTS WITH TZIELD

KEY INFORMATION ABOUT TZIELD

SUPPORT THROUGH TREATMENT

## What are THE STAGES OF T1D?

T1D is an autoimmune disease. It occurs when the immune system attacks the cells in the pancreas that make insulin, called beta cells. But T1D happens in stages. The attack on the beta cells starts before you need insulin injections. **This is called early-stage T1D.** During this stage, two or more T1D autoantibodies are present in the blood.

### EARLY-STAGE T1D

#### STAGE 1

2 or more T1D autoantibodies are present



The immune system has started attacking beta cells



Blood sugar levels are within a normal range



No insulin is needed

#### STAGE 2

2 or more T1D autoantibodies are present



Beta cells continue to be attacked



Blood sugar levels may be outside of a normal range. **This is called dysglycemia**



No insulin is needed



**WHEN THE IMMUNE SYSTEM STARTS ITS ATTACK ON BETA CELLS**, proteins called T1D autoantibodies show up in the blood. Screening for these autoantibodies can help to detect early-stage T1D.

### STAGE 3 T1D

2 or more T1D autoantibodies may be present



Beta cells are damaged and can't make enough insulin



Blood sugar levels are higher than a healthy range. **This is called hyperglycemia**



The body can't make enough insulin on its own, so taking insulin injections will eventually be needed

### IMPORTANT SAFETY INFORMATION (CONT'D)

#### What is the most important information I should know about TZIELD?

Your healthcare provider will do blood tests to check your liver and your complete blood counts before you start treatment and during treatment with TZIELD. During and after your treatment with TZIELD, your healthcare provider will check for serious side effects, as well as other side effects, and treat you as needed. Your healthcare provider may temporarily or completely stop your treatment with TZIELD, if you develop liver problems, have a serious infection, or if your blood counts stay too low.

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## TZIELD IS FOR PEOPLE 8 YEARS AND OLDER *who have Stage 2 T1D*

### ? HOW DO YOU KNOW IF YOU HAVE STAGE 2 T1D?

Stage 2 T1D means that you have tested positive for 2 or more T1D autoantibodies, have abnormal blood sugar levels, and do not have type 2 diabetes.

- Early-stage T1D can be found with a blood test. The test looks for 2 or more T1D autoantibodies
- Talk to your doctor about how to detect abnormal blood sugar levels

### ? WHO SHOULD CONSIDER GETTING SCREENED FOR EARLY-STAGE T1D?

If someone in your family has T1D, talk to your doctor about getting screened. People with a family history of T1D can have **up to a 15x greater risk of developing it**. Certain viruses (like coxsackievirus B) or autoimmune conditions (like celiac disease or Hashimoto's) may also be risk factors. And people can be diagnosed with T1D at any age.

**If you think you may be at risk for T1D, talk to your doctor about getting screened.**

#### IMPORTANT SAFETY INFORMATION (CONT'D)

**Before or after receiving TZIELD, tell your healthcare provider about all your medical conditions, including if you:**

- have a serious infection or an infection that does not go away or that keeps coming back.
- have recently received or are scheduled to receive an immunization (vaccine). TZIELD may affect how well a vaccine works. Tell your healthcare provider that you are receiving treatment with TZIELD before receiving a vaccine.

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### ? HOW CAN YOU OR YOUR LOVED ONE GET SCREENED?

There are several ways to get screened for early-stage T1D, including at a doctor's office, at certain labs, or with an at-home test kit.

**DOWNLOAD A HELPFUL GUIDE** to start the conversation with your doctor about screening options and if TZIELD could be right for you.



Actor portrayal

## TZIELD IS THE FIRST AND ONLY TREATMENT *of its kind*

It delays Stage 3 T1D for people 8 years and older with Stage 2 T1D. Talk to your doctor to see if TZIELD may be right for you or your loved one.



Actor portrayal

### *Why* DELAY STAGE 3 T1D?

A diagnosis of Stage 3 T1D can come without warning. And for many families, it's a traumatic experience with serious health complications. **With TZIELD, it may be possible to have more time before the onset of Stage 3 T1D.**

The onset of Stage 3 T1D can have a major impact for you or your child. People in Stage 3 will eventually need insulin for the rest of their lives. **More time can help you to prepare for the future.**

**YOU CAN USE THE ADDITIONAL TIME THAT YOU HAVE IN STAGE 2 T1D TO:**



Continue to live without the daily challenges of Stage 3 T1D



Prepare for T1D management in the future



Find the right doctor and care team to offer guidance and support

#### IMPORTANT SAFETY INFORMATION (CONT'D)

**Before or after receiving TZIELD, tell your healthcare provider about all your medical conditions, including if you:**

- are pregnant or plan to become pregnant. TZIELD may harm your unborn baby. Do not receive TZIELD during pregnancy and at least 30 days before a planned pregnancy.
- are breastfeeding or plan to breast feed. It is not known if TZIELD passes into your breast milk and if it can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you receive TZIELD. If you are breastfeeding, you may consider pumping and throwing away your breast milk during treatment with TZIELD and for 20 days after receiving TZIELD treatment.

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## Now it may be possible to DELAY THE ONSET OF STAGE 3 T1D

A clinical trial showed that:

With TZIELD, people had 2 more years before the onset of Stage 3 T1D, compared with placebo.

The median\* time to diagnosis was 50 months for those who were given TZIELD, compared with 25 months for those who were given placebo.

TZIELD

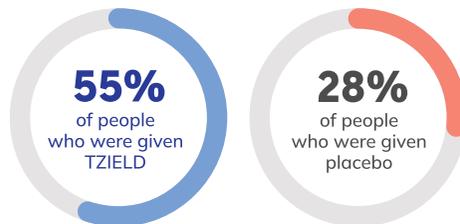
4 YEARS

PLACEBO

2 YEARS

People who had not been diagnosed with Stage 3 T1D:

More people who were given TZIELD had not been diagnosed with Stage 3 T1D by the end of the study, compared with people who were given placebo.



The clinical trial that explored the safety and effectiveness of TZIELD for delaying the onset of Stage 3 T1D included 76 people. The participants had Stage 2 T1D. 44 people in this trial were given TZIELD. 32 people in the trial were given placebo. People in the trial were followed until they were diagnosed with Stage 3 T1D. The median\* follow-up time was 51 months (just over 4 years). People not diagnosed with Stage 3 T1D were followed for different periods of time. Your results may vary.

\*Median is the middle number in a group of numbers arranged from lowest to highest.

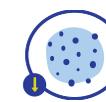
Please see Important Safety Information throughout.  
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## The most common SIDE EFFECTS OF TZIELD

In the clinical trial, the most common side effects for people who were given TZIELD included:



**RASH**  
(36% of people)



**DECREASE IN WHITE BLOOD CELL COUNTS (LEUKOPENIA)**  
(21% of people)



**HEADACHE**  
(11% of people)

**TZIELD MAY CAUSE SERIOUS SIDE EFFECTS, INCLUDING:**

### **CYTOKINE RELEASE SYNDROME**

(2% of people)

TZIELD can cause a side effect called cytokine release syndrome, or CRS. Signs and symptoms of CRS include:

- fever
- muscle and joint pain
- headache
- feeling tired (fatigue)
- nausea
- increased liver enzymes in your blood

These signs and symptoms may start during the first 5 days of TZIELD treatment. Tell your doctor right away if you develop any signs and symptoms of CRS during treatment with TZIELD.

### **DECREASE IN WHITE BLOOD CELLS (LYMPHOPENIA)**

(73% of people)

TZIELD may cause a drop in a type of white blood cell called lymphocytes. This can affect your body's ability to fight infections. A decrease in white blood cell counts can happen after your first dose and will start to go back to normal after your fifth dose of TZIELD.

**THESE ARE NOT ALL OF THE POSSIBLE SIDE EFFECTS OF TZIELD. TALK TO YOUR DOCTOR FOR MORE INFORMATION OR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS.**

The safety of TZIELD was studied in 5 clinical trials. Side effects were monitored in 773 patients who were given TZIELD and 245 patients who were given placebo. Not all of the patients in these studies had Stage 2 T1D.



## How does TZIELD WORK?

TALK TO YOUR DOCTOR TO LEARN MORE.



TZIELD attaches to certain cells in the immune system and **delays the onset of Stage 3 T1D.**



It may work by **turning off the immune system cells that attack beta cells,** which produce insulin.



**TZIELD TARGETS ONE OF THE UNDERLYING CAUSES OF T1D.**

### IMPORTANT SAFETY INFORMATION (CONT'D)

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

#### What are the possible side effects of TZIELD?

The most common side effects of TZIELD include:

- rash
- leukopenia (decrease in white blood cell counts)
- headache

These are not all of the possible side effects of TZIELD. For more information, ask your healthcare provider or pharmacist. You may report side effects to the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or 1-800-FDA-1088, or to Provention Bio at 1-844-778-2246.

Please see Important Safety Information throughout.  
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## How is TZIELD GIVEN?

TZIELD is an intravenous (IV) infusion. This means it's given through a needle into a vein in your arm.



Infusions are once a day, every day for 14 days in a row.



Each infusion is at least 30 minutes long. You will also need some extra time before and after each infusion. This is so a nurse can prepare the infusion and monitor you or your child for a short period afterwards.



If you miss a scheduled infusion, your doctor will continue your treatment on the next scheduled day. You will not receive 2 infusions on the same day.



#### MONITOR YOUR BLOOD SUGAR

After treatment with TZIELD, your doctor can help you work out how often to check your blood sugar levels and schedule follow-up appointments.





*Talk to your doctor*  
**TO LEARN MORE ABOUT TZIELD**

**DOWNLOAD A HELPFUL GUIDE TO  
START THE CONVERSATION ABOUT  
TZIELD AT YOUR NEXT APPOINTMENT.**

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Actor portrayal



Provention Bio  
**COMPASS**<sup>TM</sup>

With the Provention Bio Copay Program,\* commercially insured patients may

pay as  
 little as **\$0**

If you qualify, your COMPASS Navigator can help enroll you into the program so you can lower your out-of-pocket costs.

If you don't have insurance coverage or you cannot pay for your medicine, the Provention Bio Patient Assistance Program<sup>†</sup> may be able to help.



**A patient support program created with one goal in mind:** to assist you through the treatment process from start to finish and help make the experience as smooth as possible.

## GETTING TO KNOW YOUR COMPASS NAVIGATOR

Through one-on-one support, your dedicated COMPASS Navigator can:



Explain your insurance coverage



Provide information about financial assistance options that may be available to you



Help you understand where to get TZIELD™ (teplizumab-mzwv) infusions depending on your insurance and other factors



Answer questions about the program and offerings



Check in once treatment is completed

[Learn more](#) about our patient support program offerings.

Provention Bio COMPASS is a patient support program that helps patients to gain access to TZIELD and provides patients with education and resources related to TZIELD. Provention Bio COMPASS is not a healthcare service or an insurance provider and does not provide care coordination. Be sure to always contact your physician if you have any questions about your health or treatment with TZIELD. Provention Bio COMPASS and your COMPASS Navigator will not provide medical or treatment advice. Provention Bio COMPASS services are available only to those who have been prescribed TZIELD and are intended for US residents only.

\*This program is intended to help with the cost of TZIELD and its infusion administration only. It does not help with the cost of other medicines you take at the same time as TZIELD or with other facility fees.

<sup>†</sup>Eligibility requirements and terms and conditions apply. See [ProventionBioCompass-Copay.com](https://www.proventionbiocompass-copay.com) for more information.

# Join GENERATION TZIELD



Actor portrayal

**SIGN UP** for a program designed to provide information about treatment and the importance of early screening.

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