

# Clinical trial summary (S1905)

## Testing the Drug OBI-3424 in People with T-Cell Acute Lymphoblastic Leukemia or T-Cell Lymphoblastic Lymphoma



### What is the purpose of this clinical trial?

This trial is testing a new medicine, called OBI-3424, in people with T-cell acute lymphoblastic leukemia (T-ALL) or T-cell lymphoblastic lymphoma (T-LBL). The trial is for people whose cancer either went away and came back (relapsed) or didn't get better with treatment (refractory).

In the first part of the trial, researchers figured out the **best dose** of OBI-3424 for patients to take. (The dose is the amount of a drug you receive at one time.) They did this by carefully testing different doses of OBI-3424 to find the highest dose that isn't likely to cause serious side effects.

Now, in the second part of the study, researchers are hoping to learn **how well the medicine works**.

#### This trial is set up to find out:

- If OBI-3424 can get rid of the leukemia and lymphoma in people's bodies
- If OBI-3424 can help people live longer
- What side effects OBI-3424 might cause



### Why is this trial important?

Relapsed and refractory T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma are very hard to treat. If OBI-3424 works for people in this study, it could lead to better treatment options for patients in the future.

Researchers have tested the drug in people who have solid tumor cancers, but this is the first study to test it in people with leukemia or lymphoma.





## Who can be in this trial?

This trial is for people who have T-cell acute lymphoblastic leukemia or T-cell lymphoblastic lymphoma.

### • This trial is for people who:

- Are age 12 or older
- Have cancer that has come back or did not get better with treatment

### This trial is not for people who:

- Have an infection that isn't getting better with treatment
- Had a bone marrow transplant in the 3 months before joining the trial
- Are pregnant or breastfeeding

Talk with your doctor to learn more about who can join this study.



## What treatments will I get?

Everyone in the study will get OBI-3424. You'll receive the drug through an IV (a needle placed into a vein in your arm).

- You'll receive OBI-3424 in cycles, and each cycle will last 21 days.
- You'll get the drug on Day 1 and Day 8 of every cycle.
- You'll have as many as 17 treatment cycles. That means you'll receive treatment for as long as a year.

OBI-3424 is a new medicine that isn't approved by the Food and Drug Administration (FDA).



If the cancer doesn't get better or you're having very bad side effects, you and your doctor may decide that you'll stop getting OBI-3424.

If the cancer does get better, you and your doctor may decide it's best for you to stop treatment and get a bone marrow transplant. This is when someone gets healthy stem cells from a donor to replace their own stem cells that were damaged during cancer treatment. A bone marrow transplant is a standard treatment for people who have no signs of leukemia or lymphoma after earlier treatment.



## How long will I be in the trial?

You'll receive the study drug for up to 1 year. But you'll be in the study for **5 years** total.

After you finish treatment, you'll keep having visits with your study team. They'll check for side effects and watch to see if the cancer gets worse or comes back. At first you'll have a visit once a month, but you'll have these visits less often over time.



## Are there costs? Will I get paid?

You won't need to pay for the OBI-3424 you receive. To learn more about what costs will and won't be covered, talk to your health care provider and insurance provider.

You will not be paid for joining the study.



## Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and search the national clinical trial number: **NCT04315324**
- For a list of trial locations, visit [swog.org/NCI-S1905](http://swog.org/NCI-S1905)



## Key information

**Protocol number:** S1905

**NCT number:** NCT04315324

**Trial sponsor:** SWOG Cancer Research Network

**Publishing date:** April 24, 2025

**Full trial title:** A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL) / T-Cell Lymphoblastic Lymphoma (T-LBL)

**Thank you!**

When you join a clinical trial,  
you're moving cancer medicine and patient care forward.