

Clinical trial summary (21CTP.Leuk01)

Adding Asciminib to Usual Treatment for People with Newly Diagnosed, Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia



What is the purpose of this clinical trial?

This trial is for people who have acute lymphoblastic leukemia (ALL) that has a genetic change called the *Philadelphia chromosome*. A shorter name for this type of leukemia is **Ph+ ALL**.

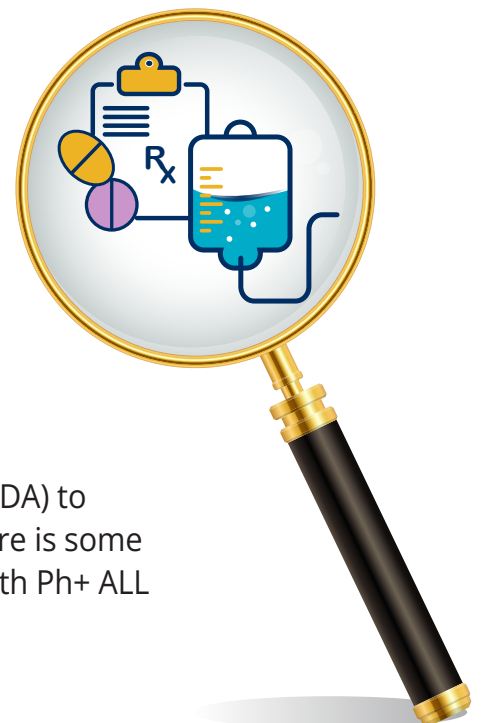
A **chromosome** is a tiny part inside cells that holds instructions for the cell. In Ph+ ALL, a piece of one chromosome breaks off and attaches to another chromosome. This change creates a protein that can make the leukemia cells grow and spread faster.

This study looks at using a drug called **asciminib**, which targets the specific protein that can cause Ph+ ALL to grow. The study will test adding asciminib to one of the treatment plans that doctors currently use for Ph+ ALL.

The researchers aim to learn if asciminib can make this usual treatment more successful at fighting Ph+ ALL and prevent it from returning.

This trial is set up to find out:

- How many people don't have any signs of leukemia in their body after 12 weeks of treatment
- How long people stay free of any signs of cancer after treatment
- What side effects people have from adding asciminib to the usual treatment for Ph+ ALL



Why is this trial important?

Asciminib has been approved by the Food and Drug Administration (FDA) to treat other types of leukemia with the Philadelphia chromosome. There is some evidence from previous research that asciminib can benefit people with Ph+ ALL as well. This trial is a chance to find out if that's true.



Who can be in this trial?

This trial is for people who have acute lymphoblastic leukemia (ALL) that has the Philadelphia chromosome.

This trial **is** for people who:

- Are age 18 or older

This trial **is not** for people who:

- Already received major treatment for Ph+ ALL (Some previous treatments to manage symptoms or help control the leukemia are OK.)
- Have poor heart, kidney, or liver function
- Are pregnant

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



What treatments will I get?

All people who join the study will receive usual treatment plus the study drug, asciminib.

You will go through up to 3 or 4 phases of treatment. The information below shows the different drug combinations that are used in each phase. Asciminib is added to Phase 1 and Phase 3.

As you go through treatment, you will have testing to check how the leukemia is responding. The test results will determine your next phase of treatment. You will stop treatment in the study if it isn't helping you.

Phase 1: Induction

asciminib (study drug) 

dasatinib 
prednisone 

Treatment lasts up to 12 weeks.

Re-induction

This treatment phase is used only if there are still signs of leukemia in your body after Phase 1.

blinatumomab 
dasatinib 

Treatment lasts up to 12 weeks.

Phase 2: Post-remission

blinatumomab 
dasatinib 

Treatment lasts up to 18 weeks.

Phase 3: Maintenance

asciminib (study drug) 

dasatinib 
prednisone 

You may continue maintenance treatment with asciminib up to 5 years after you started study treatment. You may continue dasatinib for as long as it helps you.



How long will I be in the trial?

Your part in the trial will last 5 years. How long you receive treatment in this study will depend on how the cancer responds to treatment.

Even if you stop treatment, your study team will continue to monitor your health. You will have follow-up visits until you have been in the study for a total of 5 years.



Are there costs? Will I get paid?

The study drug asciminib is provided free in this study.

Ask your health care provider and insurance provider what costs will and won't be covered in this study. You will not be paid for joining the study.



Where can I find more information about this trial?



Talk with your health care provider



Go to [ClinicalTrials.gov](https://clinicaltrials.gov) and search the national clinical trial number: NCT06773936

Key information

Protocol number:

21CTP.Leuk01

NCT number:

NCT06773936

Full trial title:

A Phase II Trial of
Asciminib, Dasatinib,
Prednisone, and
Blinatumomab for
Participants with
Newly Diagnosed
Philadelphia
Chromosome
Positive (Ph+) Acute
Lymphoblastic
Leukemia

Trial sponsor:

SWOG Clinical Trials
Partnerships (CTP)

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May 13, 2026

Thank you!

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