Enliven THERAPEUTICS

PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

ENABLE: A Phase 1a/1b Study of ELVN-001 for the Treatment of Chronic Myeloid Leukemia

Study Medicine: ELVN-001
Summary of EHA Presentation: June 2026

OVERVIEW

Researchers are studying an investigational medicine called ELVN-001 for adults with chronic myeloid leukemia (CML).

The people in this study had already received other treatments for CML, but for them, those treatments either:

did not work well enough

stopped working over time; or

caused side effects that were too difficult to tolerate

Early results from this study suggest that ELVN-001 may help lower levels of CML in the blood for people with CML. Most participants were able to continue treatment, and relatively few stopped treatment because of side effects.

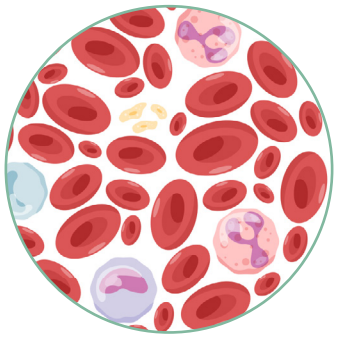
Researchers are planning to continue studying ELVN-001 in larger clinical trials.

WHAT IS CML?

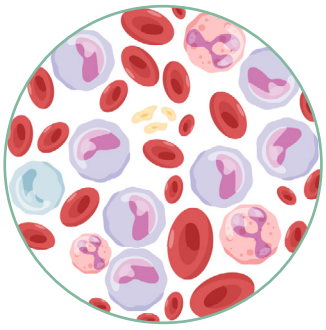
Chronic myeloid leukemia (CML) is a type of blood cancer that starts in the bone marrow, where blood cells are made.

In people living with CML, an abnormal gene called BCR::ABL1 causes the body to make too many abnormal white blood cells.

Normal bone marrow



CML bone marrow



The BCR::ABL1 gene also creates signals that tell leukemia cells to grow and survive. Many CML treatments work by blocking these signals.

CML has 3 phases:

Chronic phase

Accelerated phase

Blast phase

Most people are diagnosed and treated during the chronic phase, when the cancer is growing slowly, but symptoms start to appear.

HOW IS CML TREATED?

Most people with chronic phase CML are treated with medicines called tyrosine kinase inhibitors (TKIs).

These medicines block the BCR::ABL1 signal and can help slow or stop the growth of leukemia cells.

Several TKIs are available for CML treatment. However, some people with CML may stop treatment because for them:

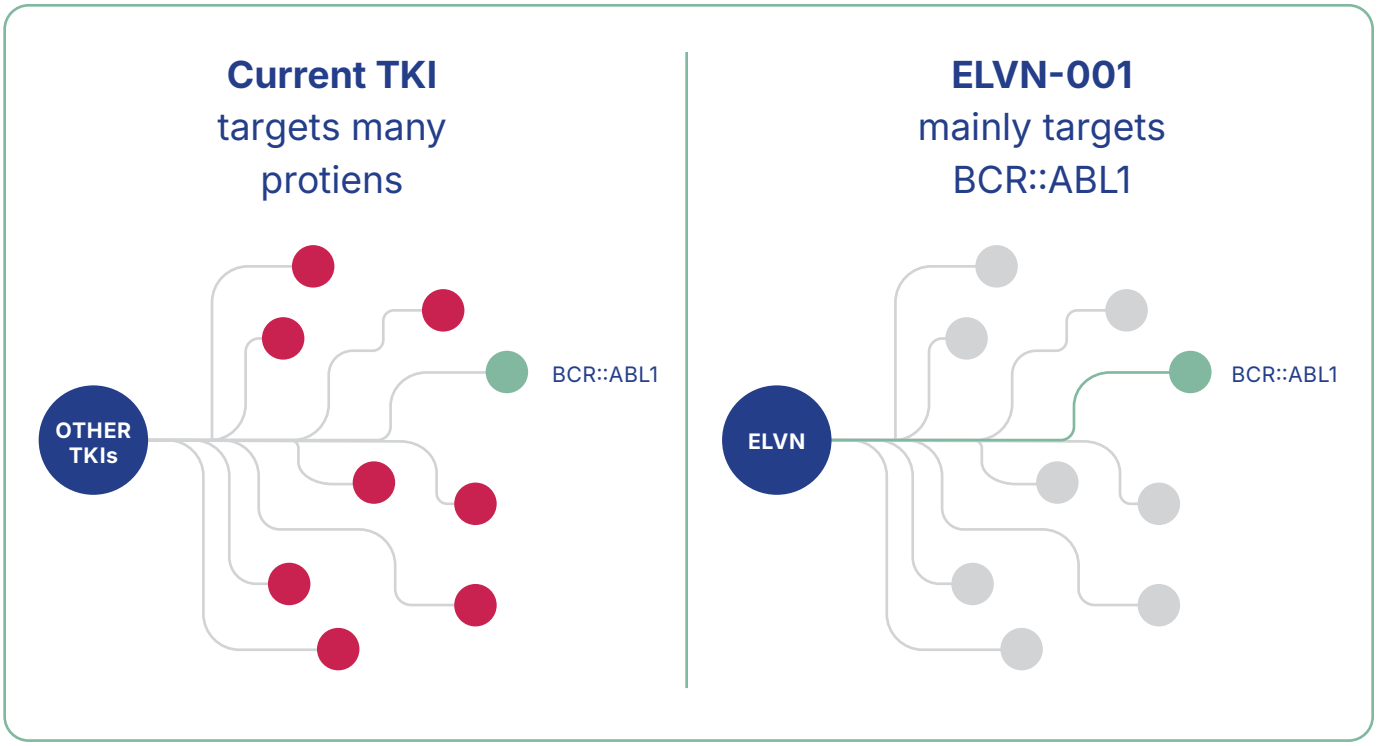
- **the medicine no longer works well**
- **the leukemia was no longer responding to treatment**
- **side effects become difficult to tolerate**

Researchers are studying new treatments to try to address these concerns.

WHAT IS ELVN-001?

ELVN-001 is an investigational medicine being studied for adults with chronic phase CML.

It is designed to mainly target the BCR::ABL1 protein while limiting effects on other proteins in the body. Researchers hope this may help reduce certain side effects seen with some other CML treatments.

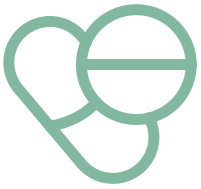


ELVN-001 has not been approved for use outside of clinical trials.

ELVN-001 is taken by mouth once daily and may be taken with or without food.

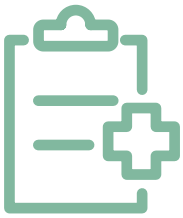
ENABLE STUDY: WHAT WAS THE PURPOSE OF THIS STUDY?

Researchers wanted to learn:



What dose of ELVN-001 could be given safely

What side effects might occur



How the medicine behaves in the body

Whether ELVN-001 lowers levels of CML in the blood

WHO TOOK PART IN THE STUDY?

As of March 10, 2026:

161 people with CML had enrolled in the study.

These people ranged in age from 19 to 82 years.

Most of these people had previously received 3 or more different TKI treatments.

About 61% had stopped their previous treatment because it did not work well enough for them.

About 32% had stopped their previous treatment because of side effects they had.

Many participants had already received other CML treatments, including asciminib or ponatinib.

HOW WAS THE STUDY DONE?

The study had two parts.

Phase 1a: Dose Escalation

Small groups of participants received increasing doses of ELVN-001.

Researchers carefully monitored side effects and treatment responses to help identify the best dose.

Phase 1b: Dose Expansion

More participants then received doses that appeared to work best and be safest for them.

Researchers identified 80 mg once daily as the recommended dose for future studies.

WHERE DID THIS STUDY TAKE PLACE?

The study took place in 14 countries across:

North America

Asia - Pacific

Europe & UK

WHAT WERE THE RESULTS OF THE STUDY?

Most participants remained in the study during the reporting period.

Among all participants (161 people with CML) in the study at the time of data cut off about:

76% were still receiving treatment.

Among participants receiving the 80 mg once-daily dose in the Phase 1b that was recommended for future studies:

82% were still receiving treatment at the time of analysis.

Among participants in either group, 6% stopped treatment because of side effects.

6% stopped treatment because of side effects

No participants progressed to blast phase CML during the study.

HOW SAFE WAS ELVN-001?

The most common reported adverse events of any cause or severity included:

15% Low platelet counts

7% Low neutrophil counts

18% Tiredness

15% Headache

14% Muscle pain

14% Joint pain

12% Nausea

11% Diarrhea

Changes in certain blood tests related to the pancreas **(lipase 22%)**

Most side effects were mild or moderate.

HOW WELL DID ELVN-001 WORK?

Researchers measured treatment response by checking the amount of BCR::ABL1 in the blood.

Lower levels of BCR::ABL1 generally mean the treatment is working.

A major molecular response (MMR) means there are very low levels of leukemia cells remaining in the blood.

Among participants receiving the 80 mg once-daily dose in the Phase 1b:

About 61% were in MMR by week 24 of treatment.

This counts all patients evaluated in the study, including those who were already in MMR when they joined the study.

About 48% reached MMR during the first 24 weeks.

This counts only patients who were not in MMR at the start and then reached it while taking ELVN-001.

All participants (100%) who already had MMR at the start of the study maintained their response.

Some participants (about 30%) even achieved deeper molecular responses (DMR).

Researchers also saw improvement in many participants who started the study with higher levels of CML in their blood.

ELVN-001 showed activity in participants who had previously received asciminib.

WHAT DO THE RESULTS MEAN?

These early study results suggest that ELVN-001 may help some people with chronic phase CML whose previous treatments did not work well enough or caused difficult side effects for them.

Most of the side effects people experienced while taking ELVN-001 were mild or moderate. Many participants were able to continue treatment, and relatively few stopped treatment because of side effects.

Researchers observed encouraging reductions in CML levels in the blood, including in people who had already received several previous CML treatments.

More research is needed to better understand the long-term safety and effectiveness of ELVN-001.

A larger Phase 3 clinical trial called ENABLE-2 is expected to begin in the second half of 2026.

Where can I learn more about this study?

If you have questions about **ELVN-001** or the **ENABLE** study, please visit:

Enliven Therapeutics: https://www.enliventherapeutics.com
ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT05304377