About komet-001

A Phase 2 clinical study for patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with the NPM1 gene mutation

Information for patients and caregivers

komet-001
ACUTE LEUKEMIAS
KURA KO-MEN-001

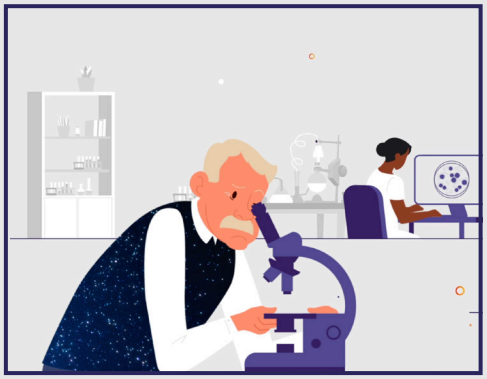
KURA ONCOLOGY

Considering Clinical Studies

Hearing that you have relapsed or that treatment hasn't worked is, understandably, very difficult. It's important to process the news and carefully consider the next steps. For example, participation in a clinical study may be one of the choices available to you.

The medical research community is constantly investigating potential new treatments through the conduct of clinical studies. Some of the important questions that clinical studies aim to answer are: Is the investigational medication safe, does it work and are its side effects tolerable? Patients who agree to take part in clinical studies help us answer these questions and more – everything we learn takes us a step closer to new and improved treatment options.

As medical research continues in AML, we're learning that different treatment paths may work better for different people. One of these potential new approaches is being tested, right now, in the KOMET-001 study. You have been given this information leaflet because your doctor believes you may be a suitable participant for this study.



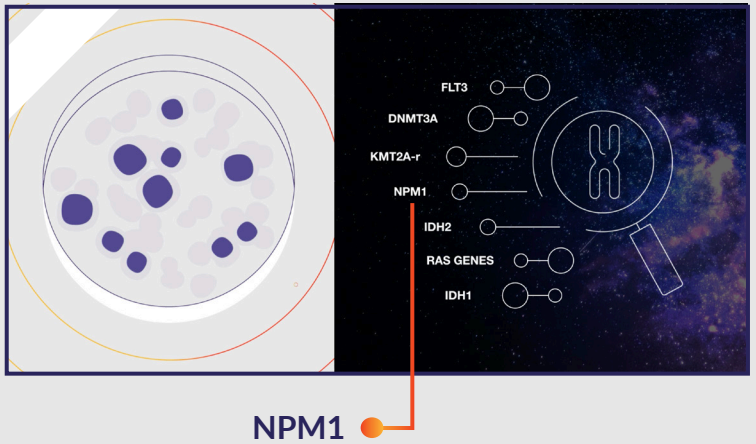
Thank you for taking the time to read about KOMET-001 and for considering taking part.

Targeting AML

Medical research helps us learn more about what may be driving cancer growth and which genes are involved. In AML, we already know that certain genetic alterations, including mutations and rearrangements, are known to drive the disease and can be used to guide treatment choice.

Furthermore, while many cancer treatments work by killing diseased cells, some of today's medical research is investigating how an emerging class of medicine could convince cancer cells to become healthy cells again.

The KOMET-001 study is assessing whether or not a targeted approach, focused on a common gene mutation in AML, can block the development of leukemia cells and persuade them to become healthy again.

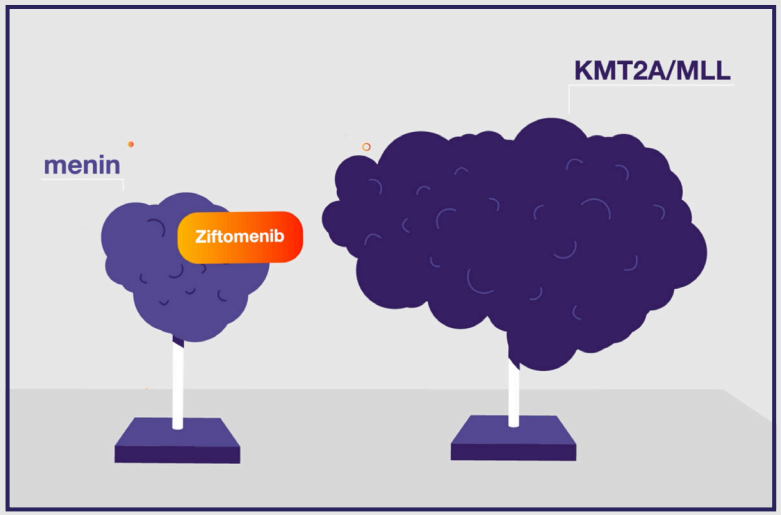


The Investigational Medication

Participants in the KOMET-001 study are receiving the investigational medication, ziftomenib – a once-daily orally administered formulation taken at home. The study is evaluating the clinical activity, safety and tolerability of ziftomenib in patients with relapsed or refractory AML that carry the nucleophosmin-1 (NPM1) gene mutation.

Ziftomenib is designed to target a protein called menin which belongs to a set of proteins known to drive acute leukemia. It aims to block the interaction of menin with these other proteins, and switch off the process that is responsible for the survival and growth of leukemia cells.

Ziftomenib belongs to a potential new class of therapies called menin inhibitors because of the way they are thought to work.



The Next Phase

The KOMET-001 study, like most clinical studies, is being conducted in phases. In the completed Phase 1 portion of the study, ziftomenib showed encouraging safety and tolerability results.

Now, doctors around the world are inviting patients with relapsed or refractory AML that carry the nucleophosmin-1 (NPM1) gene mutation to take part in the Phase 2 portion of the study.

The purpose of the Phase 2 study is to gather more information about the safety of ziftomenib and how well it is tolerated by patients, as well as to explore its potential clinical benefit in more detail.

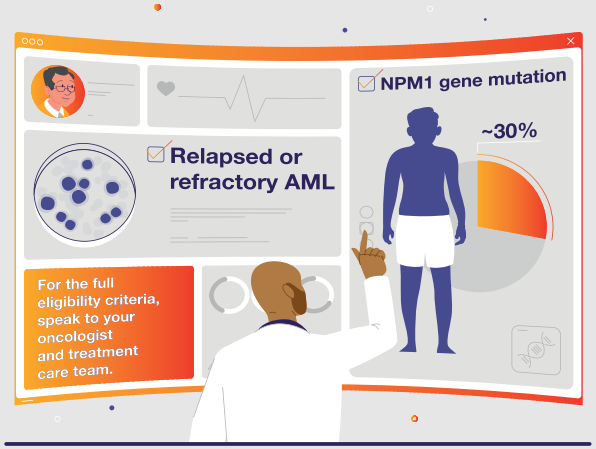
The Participation Checklist

Every clinical study has inclusion and exclusion criteria which are used to determine who can take part.

If you are interested in the KOMET-001 Phase 2 study, you will need some tests to make sure you qualify as a potential participant. These tests will be conducted and explained to you by your doctor or another member of your treatment care team.

The KOMET-001 study has 3 main eligibility criteria:

1. You must have either relapsed or refractory AML.
   - Relapsed – it has returned after a period of remission.
   - Refractory – it did not respond to treatment.
2. You must have the NPM1 gene mutation.
   - Approximately 30% of people with AML carry the NPM1 mutation.
   - Testing for the presence of this mutation is a vital part of assessing potential participants.
3. You must be at least 18 years old.



Please Ask Questions

Participation in a clinical study is a big decision and you may have questions. The team of doctors and nurses responsible for your care will make sure you know and understand what's involved every step of the way. If anything is unclear or if you have concerns at any time, don't hesitate to talk to one of them.

One of the most common questions is: Will I receive the study medication or placebo (a substance with no therapeutic effect)? The answer for KOMET-001 is simple: All participants will receive ziftomenib, which they must take once a day.

As a participant in the KOMET-001 study, you may find you are travelling to medical appointments more frequently or for longer periods of time. On the one hand, this means you are being closely monitored by the study team, but it may also have financial implications. Please talk to your treatment care team about how travel, lodging and similar expenses are paid by the study.

An important point to remember is that you can withdraw from the study at any time without having to give a reason.

The Big Picture

Every medical treatment approved for use today has been evaluated in clinical studies. Every study is carefully designed and reviewed by expert clinicians and regulatory authorities to maintain high standards of safety and scientific evaluation. And, most importantly, every patient who participates in a clinical study contributes to the advancement of medicine.

Patients who choose to take part in the KOMET-001 study are helping us gain a greater understanding of AML and the potential of the investigational medication, ziftomenib.

Please talk to your doctor or a member of your treatment care team if you are interested in taking part in the KOMET-001 study and would like to know more.

Thank you!

For more information, visit:
https://kuraoncology.com/patients-and-caregivers/acute-leukemias/