

KNOW AML

KOMET-017: *An overview*

What is KOMET-017?

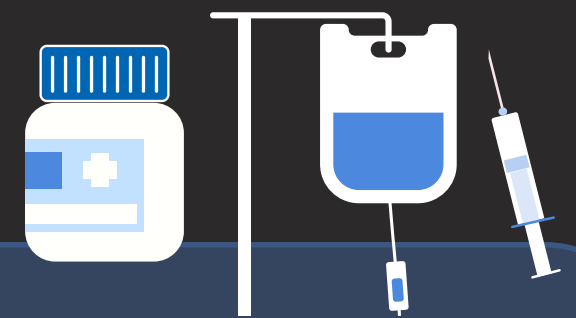
KOMET-017 is a clinical trial that is testing a medicine called **ziftomenib**.

Who is eligible?

Patients with newly diagnosed acute myeloid leukemia (AML) with particular gene changes.

What is being tested and why?

Some people with AML develop genetic changes, such as *KMT2A* or *NPM1* mutations, that help leukemia cells to grow. The cells depend on a protein called menin to survive. Medicines called menin inhibitors, such as ziftomenib, block this protein, slowing cancer growth and helping healthy blood cells recover. Ziftomenib is being tested on its own and with other AML medicines.



What is ziftomenib?



Ziftomenib is a menin inhibitor being investigated to treat AML.

It is a targeted therapy – this means it only works on cells with specific changes, rather than all fast-growing cells in the body (like some chemotherapies do).



Ziftomenib is a tablet taken once a day

Ziftomenib is used for people with AML with certain gene changes:

NPM1
mutations



or

KMT2A
rearrangements



Common side effects

The most common side effects with ziftomenib are **diarrhea** and **nausea, low blood counts**, and **infections**. Differentiation syndrome may also occur, causing symptoms such as **fever**, **fluid retention**, or **breathing difficulties**. In other clinical trials, these side effects have been manageable and often mild.

Who is eligible to take part?

The KOMET-017 trial has two therapy intensity groups; patients are put into a group by their doctor, based on their health and medical history when they join the trial:



Non-intensive therapy group

Patients aged 75 years or older OR aged 18 to 74 years with other serious health conditions.

Patients with newly diagnosed AML with a mutation in their *NPM1* gene.



Intensive therapy group

Patients aged 18 years or older and judged by their doctor to be medically fit enough to receive intensive therapy.

Patients with newly diagnosed AML with a mutation in their *NPM1* or *KMT2A* gene.

What happens during the trial?

After the therapy intensity has been decided, enrolled patients are randomly, but evenly, assigned to a treatment. Neither patients nor doctors will know which patients are receiving which treatment.

Non-intensive group

Patients will receive standard non-intensive AML treatments **venetoclax and azacitidine**



ziftomenib (group 1)

or

a placebo (group 2)

Researchers will use **standard tests** to look for signs of leukemia in the blood or bone marrow, and also see how long patients live after treatment.

Intensive group

Patients will receive standard intensive AML treatments **cytarabine and daunorubicin**



ziftomenib (group 1)

or

ziftomenib in the first two phases of treatment and **a placebo** in the final phase (group 2)

or

a placebo (group 3)

Researchers will use **highly sensitive tests** to look for signs of leukemia in the blood or bone marrow, and also see how long patients live without the cancer returning.

Key points to remember

KOMET-017 is a clinical trial testing **ziftomenib**, a new medicine for people with newly diagnosed AML who have certain changes in their genes (*KMT2A* rearrangements or *NPM1* mutations).

Ziftomenib is a **targeted treatment**. Unlike some medicines that affect all fast-growing cells, ziftomenib specifically attacks leukemia cells with certain gene changes, making it a personalized treatment based on a patient's unique genetic profile.

Patients in the trial will be assigned to either the **non-intensive therapy group** or the **intensive therapy group**, depending on their age and overall health.

The aim of the KOMET-017 trial is to find out if adding ziftomenib to standard AML treatments can help patients become **cancer-free** and remain **cancer-free for longer**, as well as to **live longer overall**.

References:

1. ClinicalTrials.gov. <https://clinicaltrials.gov/study/NCT07007312>. Updated Oct 22, 2025. Accessed Oct 24, 2025.
2. Zeidan A. Abstract #PB2573. EHA 2025 Congress; Jun 12–15, 2025; Milan, IT.
3. Fathi A. Poster Abstract #P504. EHA 2023 Congress; Jun 8–16, 2023; Frankfurt, DE.
4. Wang E, *et al.* *Lancet Oncol.* 2024;25(10):1310–1324.

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