

MK-1026-003

Learn about a clinical trial on a new drug for certain blood cancers

This brochure will tell you about a clinical trial to learn if a trial drug is safe and works well to treat these blood cancers that are all a type of B-cell malignancy:

- Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
- Richter's Transformation (RT)
- Mantle Cell Lymphoma (MCL)
- Marginal Zone Lymphoma (MZL)
- Follicular Lymphoma (FL)
- Waldenström's Macroglobulinemia (WM)

This trial is for patients whose blood cancer has come back after treatment (relapsed) or hasn't gotten better with treatment (refractory).



What are B-cell malignancy blood cancers?

The blood cancers being studied in this trial are all types of B-cell malignancies. Malignancy is another word for cancer.

A B-cell is a type of immune system cell, known as a white blood cell, which helps the body fight infections by making antibodies (substances that protect your body). B-cell malignancies happen when these cells have a mutation (change) that causes them to grow and make copies faster than normal. This leads to too many malignant B-cells in the immune system and a low number of healthy B-cells, so the body's immune system does not work as normal.


Symptoms depend on the type of B-Cell malignancy and can include:

- Swollen lymph nodes in your neck, armpits, groin, or other part of your body
- Feeling tired
- Chest pain
- Shortness of breath (feeling like you can't breathe fast enough or deeply enough to get enough air in your lungs)
- Bleeding or bruising easily
- Fever
- Night sweats
- Weight loss
- Not feeling as hungry as normal

The B-cell malignancies being studied in this trial can happen at any age but happen most often in adults over the age of 60.

What is a clinical trial?

Clinical trials are research studies designed to learn how our bodies respond to medicines or other treatments. They help doctors find out if trial drugs (alone or with other treatments) are safe and if they can prevent, find, or treat diseases, such as cancer.



Deciding to join a clinical trial is something you, those close to you, and your doctors and nurses should decide together.

Why is this trial being done?

This trial is being done to learn if the trial drug, Nemtabrutinib, is safe and effective (works well) to treat certain B-cell malignancies that have not gotten better with treatment, or that have come back after treatment. This trial will also learn about side effects that participants have when they take the trial drug.

Nemtabrutinib is still being researched and has not been approved to use alone or with other drugs to treat the B-cell malignancies being studied in this trial.

Who can join this clinical trial?

You may be able to join this trial if:

- You have one of these B-cell malignancies:
 - Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
 - Richter's Transformation (RT)
 - Mantle Cell Lymphoma (MCL)
 - Marginal Zone Lymphoma (MZL)
 - Follicular Lymphoma (FL)
 - Waldenström's Macroglobulinemia (WM)

AND

- Your B-cell malignancy has not gotten better with previous treatment (refractory) or has come back after treatment (relapsed)

There are other rules about who can join this trial. Your trial team will give you certain medical tests to make sure you qualify for the trial.

You and your trial doctor will discuss if this trial is a good option for you and the possible benefits and risks.

What drug will I get?

All participants in this trial will get the trial drug Nemtabrutinib. Nemtabrutinib is given as tablets taken once daily by mouth.

How does the trial drug work?

Nemtabrutinib is a type of targeted therapy known as a Bruton's Tyrosine Kinase Inhibitor, or BTKi, that may stop or slow cancer cell growth. Here's how it works:

1. Proteins called Bruton's Tyrosine Kinases help cancer cells in many B-cell malignancies grow, multiply, and survive.
2. The trial drug, Nemtabrutinib, blocks (inhibits) how Bruton's Tyrosine Kinase works. By blocking how Bruton's Tyrosine Kinase works, Nemtabrutinib may stop or slow cancer cell growth.

If I decide not to join this clinical trial, what are my other treatment options?

If you have a B-cell malignancy, your cancer care team will discuss your treatment options with you and those close to you. Treatment options and decisions depend on many things, such as:

- Your overall health
 - Your type of B-cell malignancy and stage of cancer
 - Other health conditions you might have
 - Side effects you might have from the treatment
 - What chance the treatment has of slowing or stopping cancer
 - How long the treatment might help extend your life
 - How much the treatment might help reduce or lessen your symptoms
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Your care team may offer you 1 or more of these treatment options:

Chemotherapy – use of medicines (drugs) to kill cancer cells

Immunotherapy – a treatment that helps the patient's immune system fight cancer

Targeted therapy – uses treatments to block a specific or unique feature that helps the cancer grow and spread

Stem cell transplant – a treatment where doctors put healthy stem cells into your body through a vein (infusion). The healthy stem cells take the place of damaged cells and make new blood cells to fight cancer.

Cell therapy – an infusion of disease-fighting cells that have been altered or designed to target cancer

Radiation – use of high energy (radiation) to kill cancer cells

Palliative care – your care team will try to make you comfortable but not treat cancer

Clinical trials, such as this one

If I join, what will happen during trial visits?

You will visit the trial site on a regular schedule so that the trial doctor can see how the trial drug is working for you. During your trial visits, you may get:

- The trial drug, Nemtabrutinib
- Blood and/or urine (pee) tests
- Physical exams
- Electrocardiograms (ECGs) (a quick, painless test that measures your heart's electrical activity)
- Imaging tests, such as CT scans, MRIs, and FDG-PET scans
- Bone marrow or lymph node biopsies (doctors take a sample of tissue from your body to test it)
- Bone marrow aspirates (doctors take a sample from the liquid part of your bone marrow to test it)

Talk to your doctor to learn more about what happens during the trial visits and how often they will happen.



Even after your treatment visits are over, the trial doctor will need to stay in contact with you through phone calls.

This is important so doctors can learn about side effects the participants have and how well the trial drug works over time.

To learn more

Talk to your study doctor or contact:

www.merckoncologyclinicaltrials.com



Clinical Trials 101 video
www.merckoncologyclinicaltrials.com

