



# A Clinical Trial for Relapsed or Refractory Diffuse Large B-Cell Lymphoma

This brochure will tell you about a clinical trial to learn if a trial drug is safe and works well to treat Diffuse Large B-Cell Lymphoma (DLBCL).

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

# What is a clinical trial?

Clinical trials are research studies that help doctors find out if trial drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions.

This clinical trial will include people (adults age 18 and over) who have been diagnosed with relapsed or refractory DLBCL that are ineligible for or have failed an autologous stem cell transplant and have also failed or are ineligible for CAR-T cell therapy.

## What is Diffuse Large B-Cell Lymphoma (DLBCL)?

DLBCL is a blood cancer of B-cells. B-cells are a type of immune system cells, known as a white blood cell, which help the body fight infections by making antibodies (substances that protect your body).

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.

DLBCL starts in those white blood cells and usually grow in lymph nodes but may also show up in other areas of the body.

Symptoms can include:

- enlarged lymph nodes
- night sweats
- unusual weight loss
- loss of appetite
- extreme tiredness or fatigue
- fever
- extreme itchiness



## Why is this trial being done?

This trial is being done to learn if the trial drug, **Zilovertamab Vedotin**, (also known as MK-2140) is safe and effective (works well) to treat DLBCL that has not gotten better with treatment, or that has come back after treatment. This trial will also learn about side effects that participants have when they take the trial drug.

Zilovertamab Vedotin is still being researched and has not been approved to use alone or with other drugs to treat DLBCL.

## Who can join this clinical trial?

You may be able to join this trial if:

- You have been diagnosed with DLBCL

**AND**

- Your cancer 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.



**Deciding to join a clinical trial is something only you, those close to you, and your cancer care team can do together.**



## What drug will I get?

You will be randomly assigned to 1 of the 2 groups. The treatment you get will depend on which group you are placed in:

**Group 1** will get the trial drug, zilovetamab vedotin plus R-GemOx (6 cycles)

**Group 2** will get R-GemOx only (6 cycles). Your doctor will be able to tell you more about this.

## How does the trial drug work?

Zilovetamab Vedotin is a type of targeted therapy known as a Tyrosine-protein Kinase receptor, or ROR1, that may stop or slow cancer cell growth. Here's how it works:

1. Cancer cells can have a protein on their outer surfaces known as receptor tyrosine kinase-like orphan receptor 1 (ROR1) that is not usually present on normal cells of the body.
2. The trial drug, Zilovetamab Vedotin, binds to ROR1, allowing the drug inside the cell.
3. Once inside the cell, the toxic molecule attached to the drug blocks the division of the cancer cell.

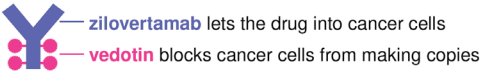
4. This may help stop or slow cancer cell growth.

5. Meanwhile, healthy cells in the body are intact.

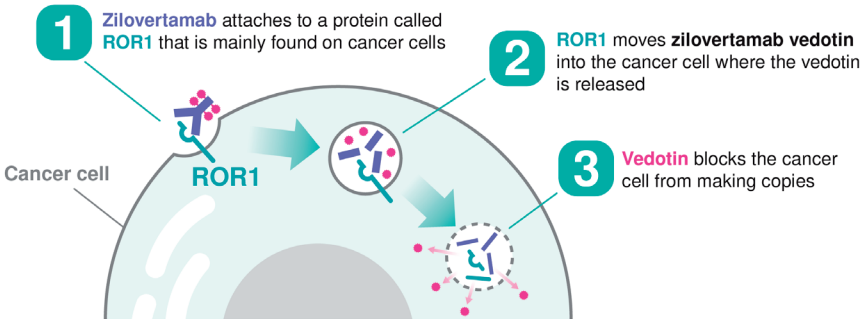
Zilovertamab Vedotin is given as intravenous (IV) infusion.

## About zilovertamab vedotin

The trial drug is made of **zilovertamab** and **vedotin**:



Here's how it works:



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

If you have DLBCL, 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 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

# 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, Zilovetamab Vidotin (depending on what group you are placed in)
- 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)



**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.

### **Contact Information:**



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

[www.merckoncologyclinicaltrials.com](http://www.merckoncologyclinicaltrials.com)



Clinical Trials 101 video  
[www.merckoncologyclinicaltrials.com](http://www.merckoncologyclinicaltrials.com)

