

# MK-1084-004

## Learn about a clinical trial for **non-small cell lung cancer (NSCLC) with KRAS G12C mutations**

In this brochure, you will learn about **non-small cell lung cancer (NSCLC) with KRAS G12C mutations** and a clinical trial for this disease. In this trial, researchers are trying to find out if an investigational study drug combined with an immunotherapy may help stop or slow down the growth of NSCLC with KRAS mutations.

You can also use this brochure to talk with your doctor about this trial.



# What is non-small cell lung cancer (NSCLC) with KRAS G12C mutations?

NSCLC is a fast-growing cancer that starts in your lungs and can spread to other organs. It is the most common type of lung cancer.

About 8 out of 10 lung cancers are NSCLC.

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## What is KRAS G12C?

People with lung cancer are often tested for gene mutations. Gene mutations are changes in your cells that affect how they work. Some mutations can cause cells to become cancerous and grow out of control.

KRAS G12C is a mutation of the KRAS protein, which is involved in cell growth. The mutation keeps the protein in an “on” state which causes cells to grow too much. This can form tumors or help tumors to grow.

KRAS G12C mutation happens in about 5% to 15% of people (5 to 15 out of 100) who have NSCLC.



**Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.**

## What are my treatment options?

If you have NSCLC, your care team will talk about your treatment options with you and those close to you.

### Your options will depend on a few things:

- Your overall health
- The stage of your cancer, which tells you if the cancer has spread and how far
- Chance of the cancer coming back
- Side effects you might have from the treatment
- What chance the treatment has of slowing down or stopping the cancer
- How long the treatment might help extend your life
- How much the treatment might help improve your symptoms

### Your care team may offer you one or more of these options:

- **Local therapies** – treatment directed at the site of the cancer to destroy it
- **Targeted therapy** – treatment that works on proteins present on tumor cells to stop them from growing
- **Immunotherapy** – medicines that help your immune system fight the cancer
- **Chemotherapy** – medicine to kill cancer cells or stop them from growing
- **Radiation therapy** – treatment that uses beams of intense energy (like X-rays) to shrink or get rid of tumors
- **Palliative care** – also called comfort care. This is special care to help ease pain and symptoms with a focus on the person's quality of life. This does not directly treat NSCLC, but it helps keep you as comfortable as possible
- **Clinical trials**, such as this one

**Talk to your doctor to find out which treatment is right for you.**

## What is a clinical trial?

Clinical trials are research studies that help doctors find out if study drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

## All about this clinical trial

### What is the goal of this clinical trial?

The goal of this trial is to learn if an investigational study medicine called MK-1084 combined with pembrolizumab may help stop or slow the growth of NSCLC with KRAS G12C mutation.

This trial is being done to test the safety and see how the body responds to the investigational study drug combined with pembrolizumab compared to those who are treated with pembrolizumab and a placebo.

A placebo looks like the study medicine but has no active ingredients. Using a placebo may help researchers better understand the real effects of the study drug.

### What is the treatment being studied?

The investigational study drug is MK-1084. Researchers are studying MK-1084 taken with pembrolizumab.

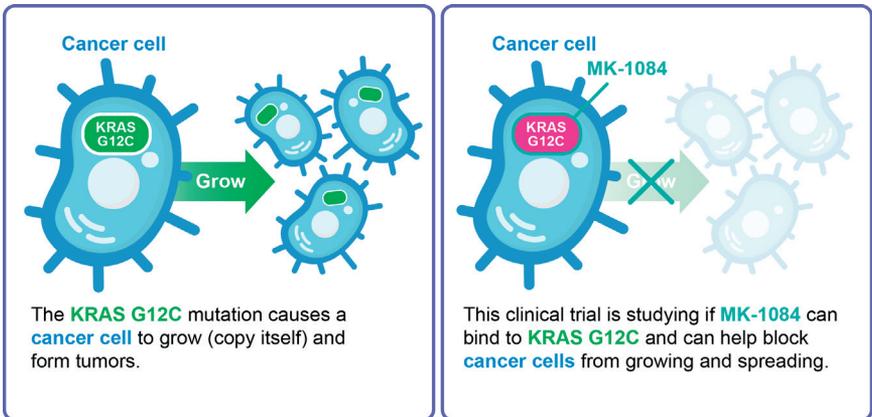
### About MK-1084

MK-1084 is an investigational study medicine. This clinical trial is studying if MK-1084 can bind to KRAS C12C and can help block cancer cells from growing and spreading.

## MK-1084:

1. The KRAS protein in cells, including lung cells, turns on and off to help control cell growth.
2. In some cancer cells, a KRAS mutation (change) called KRAS G12C keeps the protein “on”. This causes cancer cells to grow and tumors to form.
3. This is where MK-1084 comes in – researchers are studying if MK-1084 can bind with KRAS G12C and help block it.
4. By blocking the KRAS G12C mutation, MK-1084 may stop or slow down the growth of NSCLC.

## Another way to think about MK-1084



Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask your trial doctor.

## About pembrolizumab

Pembrolizumab is a type of immunotherapy, which may help the body's immune system attack cancer cells. Pembrolizumab has been approved by certain health authorities for treating various cancers, including NSCLC. It may not be approved in your country or to treat your type of lung cancer.

### Here's how pembrolizumab works:

1. A protein called PD-1 (on some of your immune system cells) sometimes binds with certain molecules called ligands (on some cancer cells)
2. When these 2 bind, it turns off the immune system cell, which means it can't do its work to help protect you and attack cancer cells
3. This is where pembrolizumab comes in – this drug binds with PD-1 and blocks PD-1 from binding with ligands
4. By blocking PD-1 from binding with ligands, pembrolizumab may help the immune system stay on so it can find and attack cancer cell

## Who can join this trial?

There are eligibility criteria that will determine if you will qualify for participation. For example, you must:

- Have been newly diagnosed with locally advanced (stage 3B or 3C) or metastatic (stage 4) NSCLC and not eligible for curative therapy such as resection, chemotherapy or radiation
- Have the KRAS G12C mutation
- Have PD-L1 protein on half, or more than half, of your tumor cells
- Not currently getting treatment for NSCLC

Your trial staff will do certain tests to see if you are able to join this trial. This will include testing a sample of your tumor for the KRAS G12C mutation and the PD-L1 protein.

### You and your trial doctor will discuss:

- All the requirements to join this trial
- Possible benefits, risks, and side effects of being in this trial

## If I join, how long will I be in the trial?

How long you will be in the trial depends on:

- Your health
- What type of cancer you have
- How well you tolerate the study treatments

## What will happen during trial visits?

You will visit the trial site on a regular schedule so that the trial doctors can see how the trial drug is working for you.

### During your trial visits, you might get:

- Blood tests
- Physical exams
- Research trial drugs
- Imaging scans such as CT scans or MRIs
- Questionnaires about how you are feeling

You can ask your trial doctor any questions you have about what happens during trial visits and how often they will happen.

If you are able to join the trial, your trial doctor will need to stay in contact with you even after your trial visits are over. This is very important because this clinical trial is studying how well the study treatment works over time.

## What treatments will I get?

The treatments you get will depend on which group you are randomly placed in.

### This trial has 2 groups:

- **Group 1** will get MK-1084 and pembrolizumab
- **Group 2** will get placebo and pembrolizumab

MK-1084 is a tablet that is taken by mouth once daily.

Pembrolizumab is given by a needle in a vein once every 3 weeks. This is called intravenous (IV) infusion. If you take the placebo, the tablet may look close to or exactly like MK-1084, but it does not contain any active ingredients.

A computer will decide which group you are put in. You have an equal chance of being in either group. You will always receive pembrolizumab, which is the standard treatment for your tumor.

You, your trial doctor, and the trial staff will not know if you are receiving the investigational study drug, MK-1084, or placebo.

