

# Keynote

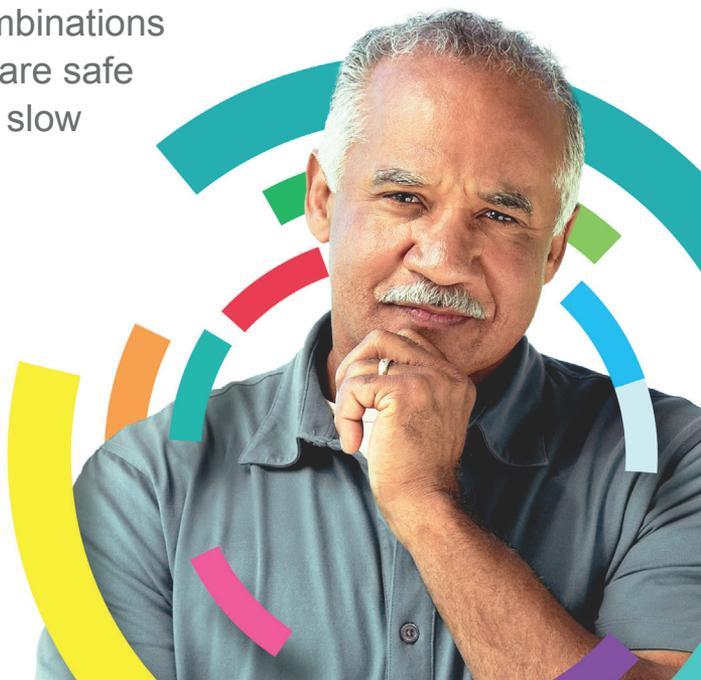


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## Learn about a clinical trial for people with **Metastatic Castration-Resistant Prostate Cancer**

In this brochure, you will learn about:

- **Metastatic Castration-Resistant Prostate Cancer**
- A clinical trial that is trying to find out if combinations of trial drugs are safe and can help slow down or stop this disease.



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## What is Metastatic Castration-Resistant Prostate Cancer (mCRPC)?

Metastatic prostate cancer is cancer that has spread from your prostate to other parts of your body. Castration-Resistant means that the cancer no longer responds to a medical or surgical treatment that lowers testosterone. It's called mCRPC for short.

Here is how mCRPC develops:

1. Male hormones (such as testosterone) help prostate cancer grow.
2. Men usually first get treatment to lower their levels of male hormones to shrink the cancer in the prostate and other areas where it has spread. This is called androgen deprivation therapy (ADT). This usually helps stop the cancer from spreading, sometimes for years.
3. However, prostate cancer eventually grows and needs more treatments to help stop it again. This is when the prostate cancer is called mCRPC.

## Your treatment options for mCRPC

If you have mCRPC, your care team will talk about your treatment options with you and those close to you. Your options will depend on a few things:

- The stage of your cancer, which tells you if it has spread and how far
- The type of prostate cancer you currently have (by looking at a sample of your tumor under a microscope). Most men will have a type of mCRPC called adenocarcinoma, and a few will have a type called neuroendocrine carcinoma.
- Your overall health
- 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 reduce your symptoms



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

- **Hormonal Agents** (for example, enzalutamide, apalutamide or darolutamide) – block the growth effect of testosterone on the tumor
- **Radiation Therapies** – use doses of radiation to kill or shrink cancer cells.

These include:

- Radium-223 – a radioactive element for cancer that has spread to the bone
- Lutetium Lu 177-Dotatate – a radioactive compound that binds to cancer cells

- **Immunotherapy, including Sipuleucel-T** – an immune therapy for men who have few or no symptoms from the cancer
- **Chemotherapy** – uses medicines that directly kill the cancer cells in your body

These include:

- Docetaxel and prednisone
- Cabazitaxel and prednisone – for prostate cancer that has worsened while on docetaxel
- Platinum based combination chemotherapy

- **Enzyme inhibitors**
  - Olaparib (inhibitor of enzyme PARP)
- **Clinical trials**, such as this one

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



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

# All about this clinical trial

## Why is this clinical trial being done?

This trial is trying to find out if combinations of trial drugs are safe and work to slow down or stop the growth of mCRPC. Researchers don't know if these combinations of drugs work to treat mCRPC.

## Who can join this trial?

If you have a type of mCRPC called adenocarcinoma, you may be able to join if you have :

- Had prostate cancer that got worse while on androgen deprivation therapy (ADT) or after bilateral orchiectomy (removal of both testicles),

**and**

- Had the chemotherapy drug docetaxel

If you have a type of mCRPC called neuroendocrine carcinoma, you may be able to join if you have:

- Had prostate cancer that got worse while on androgen deprivation therapy (ADT) or after bilateral orchiectomy (removal of both testicles)

A few men with neuroendocrine carcinoma will get treatment in this study without having another treatment first.

There are other rules that you must meet in order to join. Your study team will give you certain tests to see if you are eligible to join.

**You and your trial doctor will discuss the other rules to decide if this trial is a good option for you, as well as the possible benefits and risks of joining this trial.**

## What is the treatment being studied?

This clinical trial is studying an investigational drug called Pembrolizumab (also called MK-3475) in combination with other investigational drugs.

Pembrolizumab is a type of immunotherapy, which may help the body's immune system attack cancer cells. This immunotherapy is FDA-approved to treat other types of cancer, but is not approved to treat mCRPC.

*Note: Not all participants in this clinical trial will get Pembrolizumab + investigational drug. Some participants with a type of prostate cancer known as adenocarcinoma will only receive an investigational drug, without pembrolizumab. Some participants with a type of prostate cancer called neuroendocrine prostate cancer will receive a combination of chemotherapy drugs often prescribed for this type of cancer, without pembrolizumab.*

## What is a clinical trial?

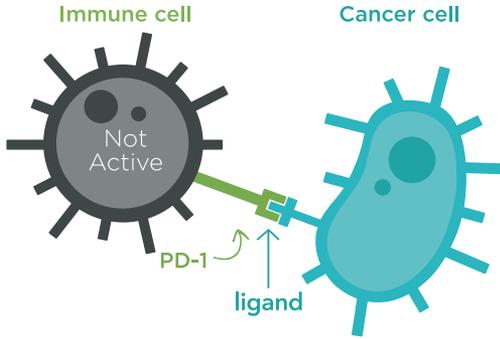
Clinical trials are research studies designed to learn how our bodies respond to medicines or other treatments. They are a way to study investigational medicines and treatments to see if they are safe and work in people.



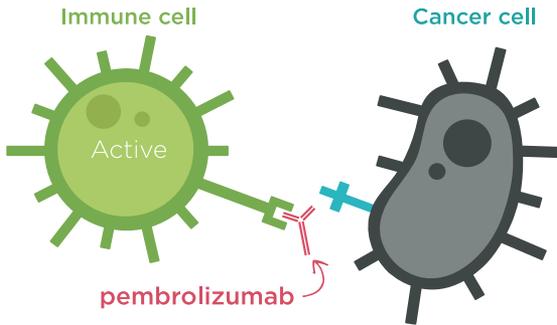
## About pembrolizumab:

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 study 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 cells

# Another way to think about the investigational treatment



When PD-1 and ligands bind, it's like turning off the immune cell. This means that the immune cell will not do its work to attack cancer cells.



This clinical trial is studying whether pembrolizumab can block PD-1 and ligands from binding so that the immune system cell stays on and can start working. Pembrolizumab will be combined with other investigational drugs that may also help attack cancer cells.

**Before deciding if you want to join, make sure you understand the potential side effects or risks. These will be explained to you by the study doctor. If there is anything you do not understand, ask the study doctor.**



**Ask your doctor any questions about what happens in the trial visits and how often they will happen**

## If I join, what will happen during trial visits?

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

- Blood and urine (pee) tests
- Physical exams
- Trial drugs
- Imaging scans such as CT scans or MRIs (scans that help the doctor see the cancer inside your body)

**If you join the trial, your study 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 drug works over time.

**Thank you for thinking about participating in this trial.** Use this brochure while discussing this study with your doctor.

Researchers use clinical trials like this one to learn more about investigational medications. The results of this study will give more information about if these trial drugs are safe and work well in people with your type of prostate cancer.

## Your questions and notes

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## To learn more

Talk to your study doctor or contact:

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



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