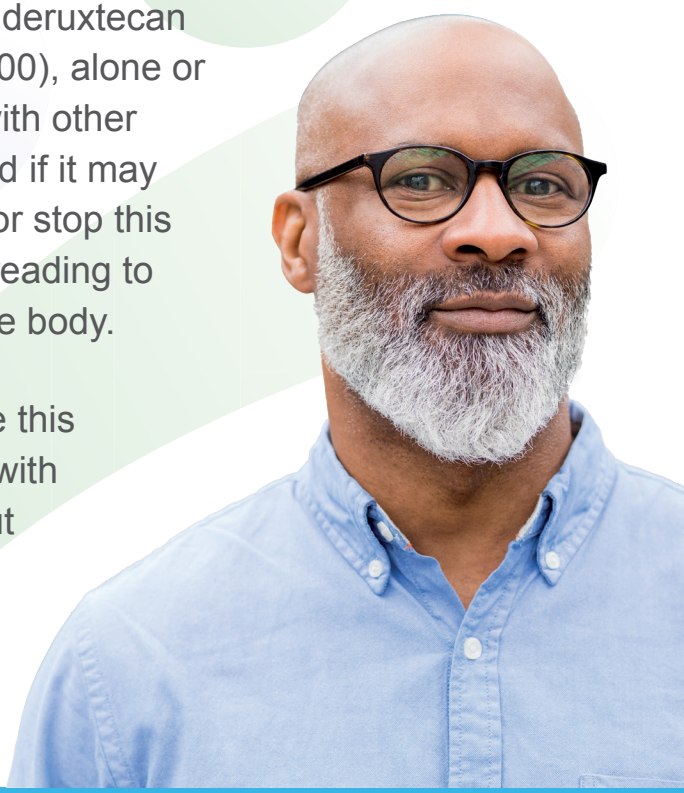
IDeate – Prostate02

MK-2400-01A

Learn about a clinical trial for **Metastatic Castration-resistant Prostate Cancer (mCRPC)**

In this brochure, you will learn about **metastatic castration-resistant prostate cancer (mCRPC)** and a clinical trial for this disease. In this trial, researchers are trying to find out if an investigational drug, ifinatamab deruxtecan (I-DXd or MK-2400), alone or in combination with other drugs, is safe and if it may help slow down or stop this disease from spreading to other areas of the body.

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



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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).
3. However, prostate cancer can eventually grow and may need more treatments to help stop it again. This is when the prostate cancer is called mCRPC.

What are my treatment options?

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:

- Your overall health
- The stage of your cancer, which tells you if it has spread and how far
- The type of prostate cancer you have. Doctors can tell what type you have by looking at a sample of your tumor under a microscope.
- Treatments you have already received for prostate cancer
- 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 1 or more of these treatments:

- **Hormone therapy** – treatment that stops hormones from helping cancer grow
- **Radiation therapy** – treatment that uses beams of intense energy (like X-rays) to shrink or get rid of tumors. This would only be used to treat symptoms related to tumor growth.
- **Immunotherapy** – medicines that help your immune system fight the cancer
- **Chemotherapy** – medicine to kill cancer cells or stop them from growing
- **Targeted therapy** – treatment that works on specific cells to stop them from growing

- **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 mCRPC, 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 the investigational trial drug, I-DXd (or MK-2400), alone or in combination with other drugs, is safe and if it may help slow down or stop this disease from spreading to other areas of the body. Participants will either receive a standard chemotherapy, (docetaxel), with another type of drug, the investigational drug, I-DXd alone or 1 of 2 investigational combinations of I-DXd with the other drugs below.

- An investigational drug, **MK-5684** – an investigational hormone therapy
- **An ARPi** (androgen receptor pathway inhibitor), either abiraterone or enzalutamide – a standard hormone therapy

I-DXd alone and the combination of I-DXd with any one of these drugs is experimental.

What treatment is being studied?

The investigational drug is ifinatamab deruxtecan (also called I-DXd, or MK-2400.

About I-DXd (or MK-2400)

I-DXd is a type of investigational targeted therapy called an antibody drug conjugate (ADC) that may destroy cancer cells.

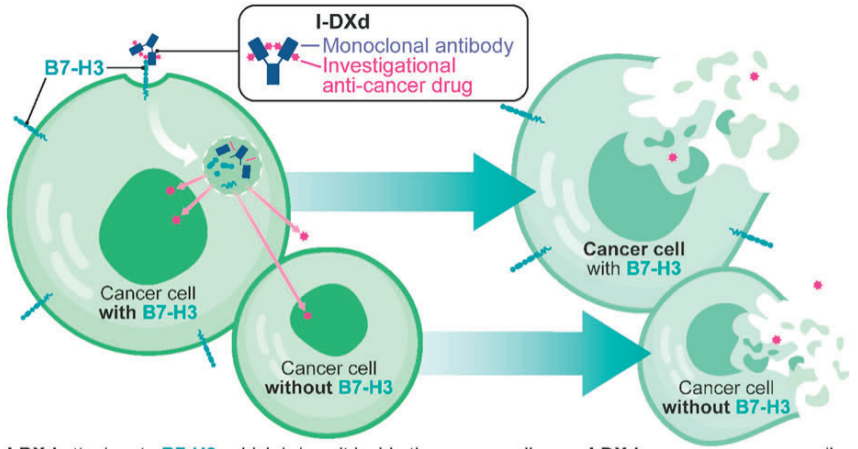
Unlike traditional chemotherapy, ADCs have 3 parts:

- **A monoclonal antibody:** A protein that binds to specific receptors (or proteins) found on certain types of cells, including cancer cells. In this case, the specific receptor is called B7H3.
- **An anti-cancer drug:** A type of drug that may lead to cancer cell death
- **Linker:** Connects the anti-cancer drug to the monoclonal antibody

About Ifinatamb Deruxtecan

1. Many types of cancer cells have proteins on their outside called B7-H3. Most healthy cells do not have B7-H3 on their outside.
2. The monoclonal antibody in I-DXd finds and binds to the B7-H3 which brings it inside the cancer cells.
3. Once inside, I-DXd breaks down and releases the investigational anti-cancer drug that may kill cancer cells.
4. The investigational anti-cancer drug may get released from the targeted cancer cells and enter nearby cancer cells without B7-H3 and cause these to die as well.

Another way to think about I-DXd



I-DXd attaches to **B7-H3**, which brings it inside the cancer cell. It then releases the **investigational anti-cancer drug**, which can also get inside nearby cancer cells **without B7-H3**.

I-DXd may cause cancer cells **with and without B7-H3** to die

What is interstitial lung disease (ILD) or pneumonitis?

I-DXd can cause interstitial lung disease (ILD), also called pneumonitis, that may be life-threatening or fatal.

ILD is when the tissue around the tiny air sacs in your lungs gets inflamed and scarred. The scarring can make it harder for your lungs to work well and can make it hard to breathe.

Signs and symptoms of ILD can include:

- Fever
- New or worsening cough
- Trouble breathing
- New or worsening shortness of breath or other breathing issues

To diagnose ILD, doctors will:

- Ask about your symptoms
- Do tests like CT scans and breathing tests
- Sometimes take a small sample of your lung tissue

Treatment for ILD includes:

- Medicines
- Oxygen therapy
- Sometimes even a lung transplant

If you join this trial and are assigned the investigational drug, I-DXd and have any signs or symptoms of ILD, **tell your trial doctor right away**. It is important to get medical treatment right away to stop ILD from getting worse.

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.

Who can join this trial?

There are eligibility criteria that will determine if you will qualify for participation.

For example, you must be at least 18 years old and have:

- mCRPC that became worse within 6 months before starting the trial and:
  - After being treated with drugs or surgery to block your testes from making hormones

  AND
  - After treatment with other drugs for prostate cancer

Your trial staff will do tests to see if you are able to join this trial.

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 study drugs are working for you.

During your trial visits, you may get:

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

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 placed in.

This trial has 4 groups:

- **Group 1:** People will get only docetaxel and prednisone or prednisolone
- **Group 2:** People will get only I-DXd
- **Group 3:** People will get I-DXd and MK-5684
    - Participants in Group 3 may also get drugs to help prevent or minimize possible side effects associated with MK-5684, including a condition called adrenal insufficiency. This is where the adrenal glands don't produce enough stress hormones. It may lead to weakness and low blood pressure. The drugs given to prevent these side effects include fludrocortisone, dexamethasone, and hydrocortisone. The trial doctor will discuss this with you.
- **Group 4:** People will get I-DXd and abiraterone or enzalutamide, and prednisone or prednisolone.

Which group you are put in depends on which groups are open at your trial site when you enroll. The trial doctor or staff will tell you which groups are open and what your chances are for being put in each of them.

You, your trial doctor, and the trial staff will know what trial treatments you are getting.

What is a tissue sample and why is it part of this trial?

To be in this trial, you will need to give a tumor tissue sample. Tissue, such as skin, hair, nails, blood, urine or tumors, are found in your body and are collected as they may help researchers understand diseases and find ways to prevent and treat them in people.

You may need to give a new tumor tissue sample, or researchers may be able to use a sample from a previous biopsy or surgery. The tissue you provide for the trial will be stored for research only and will continue to be tracked according to your trial code number.

If a new tissue sample is collected for this trial, the trial doctor will explain how it will be collected and any risks.

Some risks include:

- Low blood pressure
- Pain
- Bruising
- Redness
- Swelling
- Scarring
- Infection

There are also risks related to data privacy (please see frequently asked questions below) and the release of personal information from your health records.

Frequently asked questions about tissue collection

Will I find out the results of the research using my tissue?

This will depend on the reason for the tissue sample. You may see the results of your biomarker test (such as a biopsy or blood test) if it is required for you to join, or impacts your current participation in, the clinical trial. Results of tests performed only for research purposes will generally not be provided.

How is my privacy protected?

To protect your privacy, we take steps to limit the risk of anyone identifying you:

- We label your tissue with a number instead of your name
- We remove your name, address, phone number, social security number, date of birth and anything else that could directly identify you before researchers get access to your records or tissue sample.

If I agree to take part in the study, can I change my mind later?

Yes. You can change your mind about taking part in the trial at any time. Here's how:

1. Contact your study doctor and tell them you do not want to be in the study anymore.
2. The study doctor will contact the study Sponsor.

Tissue samples obtained up until the point of you withdrawing from the trial will continue to be retained to support the trial research.

Thank you for learning about mCRPC and this clinical trial

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

Your questions and notes:

You can use this space to write down notes or questions about this trial.

To learn more

To learn more about this trial, you can:

- Talk to your doctor
- Visit **www.merckoncologyclinicaltrials.com**
- Scan this QR code:

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