UNIVERSITY OF MICHIGAN HEALTH
MICHIGAN MEDICINE

Lu-177-PSMA-617 (Pluvicto®) Therapy Information

This handout provides information for Lu-177-PSMA-617, also known as Pluvicto®, for the treatment of metastatic castration-resistant prostate cancer (mCRPC).

What is metastatic castration-resistant prostate cancer (mCRPC)?

You have been diagnosed with **metastatic castration-resistant prostate cancer, or mCRPC**. Castration-resistant prostate cancer means that this cancer is not able to be controlled with other hormone therapy. Metastatic means that this cancer has spread (**metastasized**) in the body.

Identifying mCRPC cells in the body

- Our body's cells have **receptors** on the cell surface, which are proteins that help our cells send signals and bind to other substances to function (work) in different ways. The **metastases** (areas where cancer has spread) have receptors on the cell surface called **prostate-specific membrane antigen (PSMA) receptors**. PSMA receptor is found in high amounts on prostate cancer cells. The Pluvicto® treatment will target these cells.
- We can see the PSMA receptors on your prostate cancer cells using specific **P**ositron **E**mission **T**omography (**PET**) and **C**omputed **T**omography (**CT**) scanning. A **PET/CT scan** is a way to create pictures of organs and tissues inside the body. Having both scans at once shows us the structure of your cells and tissues and how well they are functioning. You will have scans before and after your Pluvicto® treatment to see how well it is working.

How does Pluvicto® work?

- Pluvicto® is a type of radioisotope therapy, also called **P**eptide **R**eceptor **R**adionuclide **T**herapy or **PRRT**. **Radioisotope therapy** delivers radiation directly into cancer cells by adding radioactive material (**radionuclides**) to proteins that bind with the receptors on the cancer cells and destroying those specific cancer cells.
- **Pluvicto®** is a radionuclide drug that is given to patients by injection into a vein. As the medication enters your body, it binds onto the cancer cells and delivers the radioactive material directly to the areas where the cancer has spread (metastases).
- This treatment is approved by the United States Food and Drug Administration (FD) for treatment of metastatic castration-resistant prostate cancer (mCRPC).

How will I take Pluvicto®?

We will give you Pluvicto® as an IV infusion a total of 6 different times. You will get one dose every 6 weeks, meaning that you will complete the full course of Pluvicto® therapy after 30 weeks. An **IV** is a needle or a thin tube that is inserted into a vein. The dose is injected into your body over 2-5 minutes. We may also prescribe medications to help you avoid nausea or vomiting.

How do I know if Pluvicto® treatment is right for me?

Your doctor is recommending this treatment to manage your prostate cancer because you meet the following qualifications:

- Your PET/CT scans show high PSMA receptor amounts
- You have a cancer tumor that is inoperable (cannot be treated with surgery)

To receive this treatment, you must also meet requirements for bone marrow and kidney function and general **mobility** (being able to move around and take care of yourself).

- If Pluvicto® treatment becomes toxic (causes damage) to your kidney or bone marrow, we will reduce your treatment dose or delay your next dose for another 6 weeks.
- If you continue to have issues with toxicity, we may have to stop your treatment.
- Tell your therapy team if you have urinary incontinence (you leak pee by accident). They will need to give you more specific guidelines to prevent radiation exposures to others after Pluvicto® therapy.

Is there any special preparation for this treatment?

- Get your labs done about 10-14 days before any Pluvicto® therapy appointment you have scheduled.
- We will test your kidney function (comprehensive metabolic panel), blood counts (complete blood count), and prostate-specific antigen (PSA)level before starting treatment and then before each treatment appointment after that.

What are the benefits of Pluvicto® treatment?

Research has shown that cancer treatment with Pluvicto® is more effective than treatment without Pluvicto®.

One study showing the benefit of Pluvicto® is the VISION trial. In this study, men with mCRPC were put into 2 groups with the following treatments:

- Group 1: Pluvicto® and the best care available
    - Patients received Pluvicto® every 6 weeks for up to a total of 6 doses
- Group 2: The best care available (without any Pluvicto® treatment)

In this study, patients who took Pluvicto®:

- Lived longer from the start of their treatment (those who took Pluvicto® lived about 4 months longer than those without)
- Lived longer without their cancer growing or spreading (those who took Pluvicto® lived about 5.3 months longer than those without)

What are the risks and side effects of Pluvicto® treatment?

About 2 in 10 patients, or 20%, have side effects from Pluvicto® therapy. The most common side effects are:

- Fatigue (tiredness)
- Dry mouth
- Nausea
- Anemia (low red blood cell count)
- Decreased appetite (not feeling as hungry)
- Constipation (having few or difficult bowel movements)

About 3 in 10 patients, or 30%, will have lab results that get worse after Pluvicto® therapy. The most common lab results that got worse include lower levels or counts of:

- Lymphocytes
- Hemoglobin
- Leukocytes
- Platelets
- Calcium
- Sodium

The most severe possible side effects from Pluvicto® therapy are **myelosuppression** (decrease in bone marrow function) and **renal toxicity** (decrease in kidney function).

Myelosuppression

Pluvicto® can cause severe and life-threatening myelosuppression. This is why it is very important to have your oncologist continue to monitor (watch) you closely during your therapy. We will order and review complete blood counts (lab testing) before and during your treatment with Pluvicto®. We will assess if we need to hold back, reduce your dose, or stop Pluvicto® treatment based on these results.

Renal toxicity

Pluvicto can cause severe renal toxicity. You should stay well hydrated (drink lots of fluids) and pee often before and after Pluvicto® treatment. We will order and review kidney function lab tests before and during treatment with Pluvicto®. We will assess if we need to withhold, reduce dose, or stop Pluvicto® based on these results.

What is dosimetry imaging?

Dosimetry imaging is a technique we can use to see the **biodistribution** of radionuclide from Pluvicto® within your body (where the medication has gone). We can also use it to measure the amount of Pluvicto® absorbed by the tumor tissues and your normal organ structures. We can do imaging dosimetry after your Pluvicto® therapy using a SPECT/CT camera.

The goal of imaging dosimetry is to learn how to maximize your radiation dose to tumor tissues while avoiding as much toxicity or damage to your normal organs as possible.

Do I have to follow specific instructions to prevent or manage radiation exposures to other people?

Yes, this medicine is most effective in treating your prostate cancer because it is radioactive. This is also why it is necessary to take **precautions** (actions to reduce risk or harm) to limit the radiation exposure to the people around you.

- Medical experts think the health risks to your friends, family members, and the general public are low. However, you must follow precautions for the safety of other people. These precautions are the result of many years of experience using radiation in medicine, and they include recommendations from international organizations.
- Your clinic nurse will explain the precautions you need to take and give you a handout describing them.

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