

What is PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan)?

PLUVICTO is a radiopharmaceutical used to treat adults with an advanced cancer called prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer (PSMA-positive mCRPC) that:

- has spread to other parts of the body (metastatic), and
- has already been treated with other anticancer treatments

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PLUVICTO?

Use of PLUVICTO involves exposure to radioactivity. Long-term, accruing radiation exposure is associated with an increased risk for cancer.

PLUVICTO®

Lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

Please see additional <u>Important Safety Information</u> on <u>pages 6-7</u>.



A DIFFERENT TREATMENT

After all you and your loved ones have been through, you know that **every option matters**

If you've had:

hormone therapy (pills)

1 +

+ 1

chemotherapy

Ask about PLUVICTO, a different treatment that could change your journey

Find out your PSMA status to see if PLUVICTO could be right for you

Hormone therapy: Treatment that interferes with the effects of testosterone. Chemotherapy: Treatment that uses chemicals to kill fast-growing cells in the

body. This includes cancer cells.

PSMA, prostate-specific membrane antigen.

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information I should know about PLUVICTO? (continued)

To minimize radiation exposure to others following administration of PLUVICTO, limit close contact (less than 3 feet) with household contacts for 2 days or with children and pregnant women for 7 days, refrain from sexual activity for 7 days, and sleep in a separate bedroom from household contacts for 3 days, from children for 7 days, or from pregnant women for 15 days.

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Please see additional <u>Important Safety Information</u> on pages 6-7.





WHAT IS PSMA?

PSMA (prostate-specific membrane antigen) is a biomarker that can be found on prostate cancer cells and some normal cells. If you have higher levels of PSMA, you are considered PSMA+

You can find out if you are PSMA+ by having an imaging test called a PSMA-PET scan.

>80%

of men with prostate cancer are PSMA+, so you may be as well.

WHAT IS PLUVICTO?

PLUVICTO is not chemotherapy. It is the FIRST and ONLY radioligand therapy (RLT) for PSMA+ mCRPC

- RLT is a different type of radiation therapy that is injected and that targets the biomarker PSMA
- This means it is designed to find and attack PSMA+ cells, including cancer cells* *May also damage healthy PSMA+ and other nearby cells.

Biomarker: Something that can tell your doctor more about your cancer.

PSMA-PET scan: An imaging test that can find PSMA+ cells, including prostate cancer cells, in your body.

mCRPC, metastatic castration-resistant prostate cancer; PET, positron emission tomography; PSMA+, PSMA positive.

IMPORTANT SAFETY INFORMATION (continued)

PLUVICTO may cause serious side effects, including:

- Low level of blood cell counts. Tell your doctor right away if you develop any new or worsening symptoms, including:
 - Tiredness or weakness

Please see additional <u>Important Safety Information</u> on pages 6-7.





WHY PLUVICTO?

A chance for more time with loved ones. That's a VICTORY.

The VISION trial included 831 men with PSMA+ prostate cancer that spread outside their prostate. They were divided into 2 groups:

- 551 men were treated with PLUVICTO plus standard therapy*
 - PLUVICTO was given once every 6 weeks for up to 6 treatments
- 280 men were treated with standard therapy alone

In VISION, PLUVICTO was shown to:

15 months

Help patients live longer

Median overall survival (OS) was about **15 months** for men on PLUVICTO plus standard therapy compared to about **11 months** on standard therapy alone.

9 months

Give people more time without cancer worsening

Median radiographic progression-free survival (rPFS) was about **9 months** for men on PLUVICTO plus standard therapy compared to about **3.5 months** with standard therapy alone.[†]

30% of men

Help tumors shrink or disappear

On PLUVICTO plus standard therapy, **30%** of men saw their tumors shrink or disappear compared to **2%** with standard therapy alone.

This data point is called overall response rate (ORR), which is calculated by adding complete response (CR) and partial response (PR), which was:

- CR: 6% with PLUVICTO vs 0% with standard therapy
- PR: 24% with PLUVICTO vs 2% with standard therapy

The most common side effects of PLUVICTO include:

- Tiredness
- Dry mouth
- Nausea
- Low red blood cell count
- Loss of appetite

- Changes in bowel movements (constipation or diarrhea)
- Vomiting
- · Low blood platelet count
- Urinary tract infection
- Weight loss
- Abdominal pain



Please see additional <u>Important Safety Information</u> on pages 6-7.



^{*}Standard therapy was chosen by a doctor from among existing approved treatments and did not include chemotherapy, immunotherapy, systemic isotopes like radium-223 (223Ra), or drugs still being studied.

[†]rPFS results may be misread. In the clinical trial, many patients treated with standard therapy alone dropped out early.

What to expect WITH PLUVICTO

Before treatment:

 A PSMA-PET scan will check for PSMA+ cells, including prostate cancer cells, in your body

• If your doctor decides that PLUVICTO is right for you, they will refer you to a different doctor. You will probably see a **radiation oncologist** or **nuclear medicine specialist** at a treatment center to receive PLUVICTO

During treatment, PLUVICTO is:

• Given through an intravenous (IV) injection or infusion

• Given every 6 weeks for up to 6 doses

 Your body, blood, sweat, and urine give off radiation for a while after getting PLUVICTO. Your doctor will give you instructions to help reduce overall exposure to yourself and others

- PLAN AHEAD -

Find <u>treatment centers</u> in your area.

IMPORTANT SAFETY INFORMATION (continued)

PLUVICTO may cause serious side effects, including (continued):

- Pale skin
- Shortness of breath
- Bleeding or bruising more easily than normal or difficulty stopping bleeding
- Frequent infections with signs such as fever, chills, sore throat, or mouth ulcers

Please see additional <u>Important</u> <u>Safety Information</u> on <u>pages 6-7</u>.

vipivotide tetraxetan **NEXT**

PREVIOUS

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PLUVICTO may cause serious side effects, including:

- Low level of blood cell counts. Tell your doctor right away if you develop any new or worsening symptoms, including:
 - Tiredness or weakness
 - Pale skin
 - Shortness of breath
 - Bleeding or bruising more easily than normal or difficulty stopping bleeding
 - Frequent infections with signs such as fever, chills, sore throat, or mouth ulcers
- Kidney problems. Tell your doctor right away if you develop any new or worsening symptoms, including passing urine less often or passing much smaller amounts of urine than usual



Please see full Prescribing Information here.



IMPORTANT SAFETY INFORMATION (continued)

Before you receive PLUVICTO, tell your doctor if any of these apply to you:

- You have low level of blood cell counts (hemoglobin, white blood cell count, absolute neutrophil count, platelet count)
- You have or have had tiredness, weakness, pale skin, shortness of breath, bleeding or bruising more easily than normal or difficulty stopping bleeding, or frequent infections with signs such as fever, chills, sore throat, or mouth ulcers (possible signs of myelosuppression)
- · You have or have had kidney problems
- You have or have had any other type of cancer or treatment for cancer, as PLUVICTO contributes to your long-term cumulative radiation exposure
- You are sexually active as:
 - All radiopharmaceuticals, including PLUVICTO, have the potential to cause harm to an unborn baby
 - You should use effective contraception for intercourse during treatment with PLUVICTO and for 14 weeks after your last dose
 - PLUVICTO may cause temporary or permanent infertility

Before administration of PLUVICTO, you should drink plenty of water in order to urinate as often as possible during the first hours after administration.

The most common side effects of PLUVICTO include:

- Tiredness
- Dry mouth
- Nausea

PREVIOUS

- Low red blood cell count
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- Changes in bowel movements (constipation or diarrhea)

- Vomiting
- Low blood platelet count

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- Urinary tract infection
- Weight loss
- Abdominal pain

These are not all of the possible side effects of PLUVICTO. Call your doctor for advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information here.



What could PLUVICTO do for you?



Talk to your doctor about PLUVICTO. Use the <u>DISCUSSION GUIDE</u> to prepare.

Please see <u>Important Safety Information</u> on <u>pages 6-7</u>.





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