





THERE'S

A chance for more everyday VICTORIES.

Men who received PLUVICTO plus standard therapy **lived longer** with a median of **15 months** vs **11 months** with standard therapy alone.\*

**30%** of men who received PLUVICTO plus standard therapy saw their tumors shrink or disappear (vs **2%**).

That means more time for the people and things important to you.

Actor portrayal.

# Guidance along your journey with PLUVICTO

\*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.

### 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.

Please see additional Important Safety Information on pages 19-20.

**NEXT** 



# MENU

It's normal to have questions when starting a new treatment, especially when it works differently than other treatments.

This guide can answer questions you may have about treatment with PLUVICTO.

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## **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.





# ASK FOR SOMETHING DIFFERENT

After all you and your loved ones have been through, you know that every treatment matters.

If you've had:

therapy (pills)

1 + 1 = Ask about PLUVICTO, a different treatment that chemotherapy could change your journey.

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

PSMA, prostate-specific membrane antigen.

### 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
  - 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

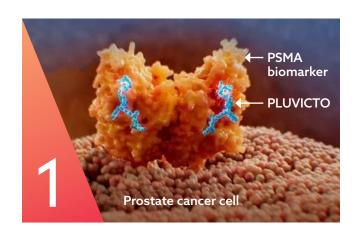




# PLUVICTO is the FIRST and ONLY RLT for PSMA+ mCRPC

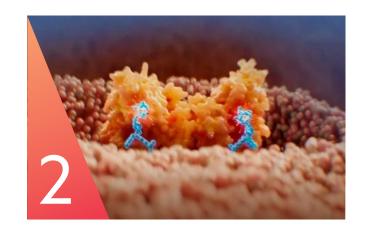
**PLUVICTO** is not chemotherapy. RLT is a different type of radiation therapy that is injected and that targets a biomarker called PSMA, which is present on many prostate cancer cells and also some healthy cells. PLUVICTO is designed to find and attack PSMA+ cells, including cancer cells.\*

## Remember it in 3 steps:



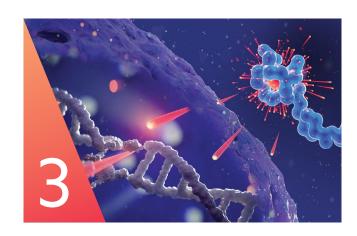
### ATTACH:

PLUVICTO attaches to PSMA proteins on the outside of a cell.



### **ABSORB:**

Then PLUVICTO is absorbed into the cell.



### ATTACK:

From inside the cell, PLUVICTO attacks. It releases radiation into its target, the PSMA+cell, damaging or destroying it with limited damage to surrounding cells.\*

**NEXT** 

## If you are PSMA+, PLUVICTO could be right for you.

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

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

\*May also damage healthy PSMA+ and other nearby cells.

## IMPORTANT SAFETY INFORMATION (continued)

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

• 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

# 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)











PROVEN RESULTS: PLUVICTO MAY HELP YOU

# LIVE LONGER

## Overall Survival (OS)

PLUVICTO plus standard therapy

(551 men evaluated)

15 MONTHS

Standard therapy alone (280 men evaluated)

MONTHS

The VISION clinical trial measured OS. Median OS is the length of time half of the men in the study were still alive.

Results have been rounded from 15.3 to 15 months and 11.3 to 11 months.

VISION 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

### **IMPORTANT SAFETY INFORMATION (continued)**

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

- 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

<sup>\*</sup>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.





PROVEN RESULTS: PLUVICTO MAY HELP YOU HAVE

# MORE TIME WITHOUT CANCER WORSENING

Radiographic Progression-Free Survival (rPFS)

9

PLUVICTO plus standard therapy (385 men evaluated)

MONTHS

3.5
Standard therapy alone MONTHS

(196 men evaluated)

The VISION clinical trial measured rPFS. Median rPFS is the time when half of the men in the study were still alive without their cancer spreading or getting worse.\*

Results have been rounded from 8.7 to 9 months and 3.4 to 3.5 months.

\*rPFS results may be misread. In the clinical trial, many patients treated with standard therapy alone dropped out early, so the PLUVICTO-treated patients provided more information.

### **IMPORTANT SAFETY INFORMATION (continued)**

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







Please see additional Important Safety Information on pages 19-20.

1-800-FDA-1088.





PROVEN RESULTS: WITH PLUVICTO

# TUMORS ARE MORE LIKELY TO SHRINK

## Overall Response Rate (ORR)

Percentage of men who saw their tumors shrink or disappear

30%

PLUVICTO plus standard therapy

(319 men evaluated)



Standard therapy alone

(120 men evaluated)

The VISION trial measured ORR, which measures the impact of PLUVICTO on tumors. It includes complete response (CR) and partial response (PR).

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

ORR was the percentage of men who saw their tumors shrink (PR) or disappear (CR).

#### **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.





# PSA RESPONSE\*

The VISION trial also measured the percentage of men whose PSA levels dropped by at least 50%.

## Prostate-Specific Antigen (PSA) Response

Percentage of men who had at least a 50% drop in PSA

46%

PLUVICTO plus standard therapy

(385 men evaluated)

7%

Standard therapy alone

(196 men evaluated)

If the PSA was 100 ng/mL before the clinical trial, then VISION would measure the PSA level if it dropped to 50 ng/mL or lower.\*

\*Measuring PSA response was not the main goal of the VISION trial. It was not statistically significant. It does not impact the results for OS or rPFS.

# 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.







# PLUVICTO is given in up to 6 DOSES

### Each dose:

- · Will be given in 1 of 2 ways: through an intravenous (IV) injection or infusion
- Is given once every 6 weeks



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

### **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
  - o 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





# What to expect BEFORE EACH DOSE



### Your health care team

While on treatment with PLUVICTO, a team of doctors will work together to make sure you are taken care of. You will also get support from nurses and other health professionals.

### Below are doctors that may be a part of your care team:

- A medical oncologist, who treats cancer with chemotherapy, hormone therapy, and immunotherapy
- A urologist, who treats urinary system and male reproductive system diseases
- A radiation oncologist, who treats cancer with radiation therapy
- A nuclear medicine doctor, who focuses on diagnosing and treating diseases using radioactive materials

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

### IMPORTANT SAFETY INFORMATION (continued)

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

• 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

# 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)





# What to expect BEFORE EACH DOSE (continued)



### Lab tests

You will continue to have some tests done, like blood work, before and during treatment. Your first test will be performed a few days before your first dose with PLUVICTO.



## **Hydrating**

Drink plenty of water before and after each dose. This will help get rid of extra radiation in your body.

### **IMPORTANT SAFETY INFORMATION (continued)**

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

- 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





# What to expect AFTER EACH DOSE



## Reduce radiation exposure

Your body, blood, sweat, and urine give off radiation for a while after getting PLUVICTO. Always follow your doctor's instructions. Also, here are some tips to help reduce overall exposure to yourself and others:



### **Distancing**

Limit close contact (less than 3 feet) with others after each dose. Stay apart longer from some higher-risk groups. Ask your doctor for more information.



Stay hydrated and urinate (pee) as much as you can



Sleep in a separate bedroom



No sexual activity for 7 days. Use protection after that

## **IMPORTANT SAFETY INFORMATION (continued)**

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

- 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





# Understanding PLUVICTO SIDE EFFECTS

It's normal to have concerns about side effects when starting a new treatment. Speak with your care team about any side effects you may be experiencing. You should also ask any questions you may have.

#### 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

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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>, or call 1-800-FDA-1088.

## Talk to your CARE TEAM.

Your health care provider may temporarily delay your next dose, decrease your dose, or completely stop your treatment with PLUVICTO if you develop certain serious side effects.







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





## **Novartis Patient Support™**

Once you and your health care provider decide to begin PLUVICTO, Novartis Patient Support is here to help.

### We can help you:



Navigate the insurance process



Get financial support\*



Find answers to questions across the treatment journey

If you have already been prescribed PLUVICTO, sign up for Novartis Patient Support.



Call 1-844-638-7222, Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays. Ask your health care provider to help you sign up for assistance.

### **Get financial support\***

If you have private insurance, you could be eligible for Co-Pay Plus and pay as little as \$25 for your PLUVICTO treatment.

\*Limitations apply. Valid only for those patients with commercial insurance. Not valid under Medicare, Medicaid, or any other federal or state program. Offer subject to a maximum benefit per course of treatment. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms and Conditions in the enrollment forms for details.

## **IMPORTANT SAFETY INFORMATION (continued)**

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Please see full Prescribing Information here.





# Important Safety Information (continued)

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- You have low level of blood cell counts (hemoglobin, white blood cell count, absolute neutrophil count, platelet count)
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**NEXT** 

# Glossary

Understanding key terms related to your treatment is important. It will help you know what to expect while taking PLUVICTO and can also help you communicate with your care team.

Term	Definition
Biomarker (page 5)	Something that can tell your doctor more about your cancer.
<b>Chemotherapy</b> (pages 1, 4, 5, 7, 13)	Treatment that uses chemicals to kill fast-growing cells in the body.
Complete response (CR) (page 10)	When tumors disappear with treatment.
Hormone therapy (pages 1, 4, 13)	Treatment that interferes with the effects of testosterone.
Low blood platelet count (pages 9, 16, 18, 20)	Possible side effect of PLUVICTO, someone with low blood platelet count struggles to stop bleeding. This could mean you bruise easily or bleed more than usual from a small cut.
Low red blood cell count (pages 9, 16, 18, 20)	Possible side effect of PLUVICTO, a low blood cell count affects your ability to fight infections. Symptoms may include tiredness, shortness of breath, and chest pain.
Metastatic castration- resistant prostate cancer (mCRPC) (pages 1, 5, 19, 23)	A type of advanced prostate cancer that has spread outside the prostate. It also no longer responds as well to certain hormone treatments.
Overall response rate (ORR) (page 10)	The total percentage of patients whose cancer responds to treatment. Their tumors disappear or shrink in size.
Overall survival (OS) (pages 7, 11)	Measure of how long patients live after they are assigned treatment in a clinical trial.

Please see <u>Important Safety Information</u> on <u>pages 19-20</u>.





# Glossary (continued)

Term Definition

Partial response (PR)

(page 10)

When a treatment decreases a tumor's size.

Prostate-specific antigen (PSA)

(page 11)

A substance made by the prostate that may be found in higher-than-normal levels in the blood of men who have prostate cancer. PSA levels are found through a blood test.

Prostate-specific membrane antigen (PSMA)

(pages 1, 4, 5, 7, 19, 23)

A biomarker commonly found on the outside of prostate cancer cells, and some normal cells. A PSMA-PET scan can find PSMA+ cells in your body.

**PSMA-PET** scan

(page 5)

An imaging test that can help find PSMA+ cells, including prostate cancer cells,

in your body.

Radiographic progressionfree survival (rPFS)

(pages 8, 11)

In a clinical trial, how long patients live without their cancer getting worse. It is determined by imaging tests.







# STAY IN TOUCH with your health care team

if you have any questions about your treatment.



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