PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

DISCOVER THE POSSIBILITIES OF EARLY PSMA-PET SCANS

Precision diagnostics to inform targeted treatment with PLUVICTO® at the earliest eligible opportunity

Indications

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated in combination with androgen receptor pathway inhibitor (ARPI) therapy for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer.

PLUVICTO is indicated for the treatment of adult patients with PSMA-positive metastatic androgen pathway modulation-resistant (mAPMR) prostate cancer who have been treated with ARPI therapy, and

- are considered appropriate to delay taxane-based chemotherapy, or
- have received prior taxane-based chemotherapy.

IMPORTANT SAFETY INFORMATION

Risk From Radiation Exposure

- PLUVICTO contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk for cancer.
- Minimize radiation exposure to patients, medical personnel, and others during and after treatment with PLUVICTO consistent with institutional practices, patient treatment procedures, Nuclear Regulatory Commission patient-release guidance, and instructions to the patient for follow-up radiation protection.
- Ensure patients increase oral fluid intake and advise them to void as often as possible to reduce bladder radiation.
- To minimize radiation exposure to others, advise patients to limit close contact (less than 3 feet) with others for 2 days or with children and pregnant women for 7 days, to refrain from sexual activity for 7 days, and to sleep in a separate room from others for 3 days, from children for 7 days, or from pregnant women for 15 days.

Please see additional Important Safety Information throughout and on pages 6-7 and full Prescribing Information.

PSMA IS A KEY BIOMARKER FOR DETECTING AND TARGETING METASTATIC PROSTATE CANCER

- PSMA serves as an actionable biomarker, providing an accessible target for ligand binding for BOTH imaging and treatment[1,2]
- PSMA-PET imaging demonstrates high sensitivity and specificity for detecting PSMA+ metastases compared to conventional imaging[3-6]
  - PSMA is not appreciably released into circulation, enabling specific targeting of PSMA-expressing cells and lesions with radioligands[2]

MORE THAN 80%

OF MEN WITH PROSTATE CANCER OVEREXPRESS THE PSMA BIOMARKER[7,8]

SCAN EARLY FOR PSMA EXPRESSION TO HELP DETERMINE ELIGIBILITY FOR PSMA-TARGETED THERAPY[9]

PSMA, prostate-specific membrane antigen; PSMA+, PSMA positive; PET, positron emission tomography.

IMPORTANT SAFETY INFORMATION (continued)

Myelosuppression

- PLUVICTO can cause severe and life-threatening myelosuppression. In clinical trials (PSMAddition, PSMAfore, VISION) grade 3 or 4 decreased hemoglobin (ranged from 4.3-15%), decreased leukocytes (4.4-7%), decreased neutrophils (3.5-4.5%), and decreased platelets (1.1-9%) occurred in patients treated with PLUVICTO. 5 myelosuppression-related deaths have occurred, including one due to bone marrow failure during long-term follow-up.
- Perform complete blood counts before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of myelosuppression.

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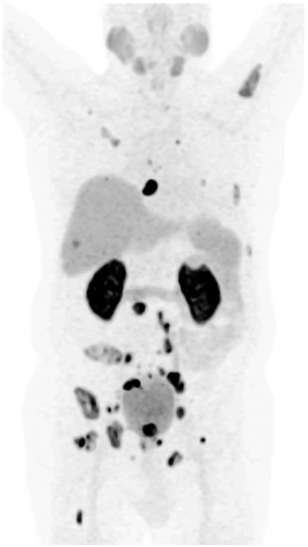
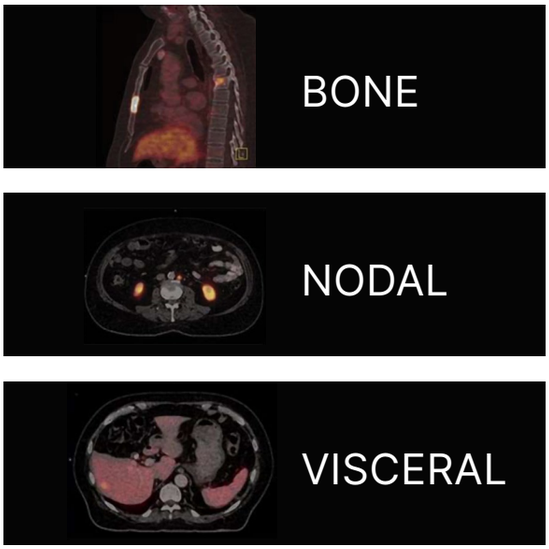
IDENTIFY PSMA+ mPC EARLY TO OPEN THE DOOR TO TARGETED RLT AS EARLY AS mAPMN/S PC (also known as mHSPC)

With PSMA-PET confirmation of PSMA expression, patients can access targeted therapy with PLUVICTO[1]

- PLUVICTO is proven in three large phase 3 clinical trials.* And [~30k] patients treated since FDA approval[10-13,†]

PLUVICTO delivers DNA-breaking radiation directly to PSMA+ cells, regardless of where they have metastasized (bone, nodal, or visceral)[1]





REFER PATIENTS WITH CONFIRMED PSMA+ mPC TO A SPECIALIZED TREATMENT CENTER: PLUVICTO + ARPI FOR mHSPC, OR PLUVICTO AFTER 1 PRIOR ARPI IN mAPMR PC (ALSO KNOWN AS mCRPC)[1]

ARPI, androgen receptor pathway inhibitor; mAPMN/S PC, metastatic androgen pathway modulation-naive or -sensitive prostate cancer; mAPMR PC, metastatic androgen pathway modulation-resistant prostate cancer; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; mPC, metastatic prostate cancer; RLT, radioligand therapy.

*PLUVICTO was studied in 1 clinical trial of mHSPC and 2 clinical trials of mCRPC.[1]
†Based on data from [March 2026].[13]

IMPORTANT SAFETY INFORMATION (continued)

Renal Toxicity

- PLUVICTO can cause severe renal toxicity. In clinical trials grade 3 or 4 acute kidney injury (ranged from 1.3-3.4%) occurred in patients treated with PLUVICTO.
- Advise patients to remain well hydrated and to urinate frequently before and after administration of PLUVICTO. Perform kidney function laboratory tests, including serum creatinine and calculated creatinine clearance (CrCl), before and during treatment. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of renal toxicity.

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NCCN CLINICAL PRACTICE GUIDELINES IN ONCOLOGY (NCCN GUIDELINES®) RECOMMENDATION

NCCN RECOMMENDED

Because of increased sensitivity and specificity, PSMA-PET scans are recommended by the National Comprehensive Cancer Network® (NCCN®) as an alternative to standard imaging throughout the prostate cancer journey[14]

- At **initial staging**[14]
- For **detection** of biochemically recurrent disease[14]
- To **evaluate progression**[14,*]
- To **establish eligibility** for lutetium Lu 177 vipivotide tetraxetan (PLUVICTO)[14]
  - Progression in mCRPC after 1 ARPI

CT, computed tomography; MRI, magnetic resonance imaging.

*With bone scan plus CT or MRI for the evaluation of bone, pelvis, and abdomen.[14]

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

IMPORTANT SAFETY INFORMATION (continued)

Embryo-Fetal Toxicity

- The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, radioactive emissions, including those from PLUVICTO, can cause fetal harm. Advise males with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose.

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CLINICAL EVIDENCE CONFIRMS THE UTILITY OF PSMA-PET ACROSS THE CONTINUUM OF mPC

Across multiple trials, PSMA-PET testing has helped refine mPC patient care

>50%

RECEIVED MORE ACCURATE STAGING[15,16]

• Upstaged from M0 to M1

In a **phase 3 clinical trial** of men with biochemically recurrent prostate cancer (N=1960).[15,17]

In **OSPREY**, a phase 2/3 clinical trial of PSMA-PET scans in men with suspected recurrent or metastatic prostate cancer (N=385).[16]

4 out of 10 patients

HAD THEIR DISEASE RECLASSIFIED MORE ACCURATELY (N=27/67)[18]

In **CHAARTED to PSMA PET**, an international, multicenter, retrospective study of PSMA-PET scans vs conventional imaging in men with mHSPC (N=67).[18]

~2/3

HAD A CHANGE IN INTENDED DISEASE MANAGEMENT PLAN (N=131/205)[19]

In **CONDOR**, a phase 3 clinical trial of PSMA-PET scans in men with biochemically recurrent prostate cancer (N=208).[19]

In patients with M0 CRPC, a positive PSMA-PET scan alone should not be the sole factor in changing systemic therapy.

CRPC, castration-resistant prostate cancer.

IMPORTANT SAFETY INFORMATION (continued)

Infertility

- The recommended cumulative dose of 44.4 GBq of PLUVICTO results in a radiation-absorbed dose to the testes within the range where PLUVICTO may cause temporary or permanent infertility.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

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IMPORTANT SAFETY INFORMATION (continued)

Infertility

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Adverse Reactions and Laboratory Abnormalities

- In the pooled safety population for the PSMAddition, PSMAfore and VISION studies (N=1320), the most common (≥20%) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (86%), decreased hemoglobin (68%), fatigue (51%), dry mouth (46%), decreased neutrophils (35%), nausea (35%), decreased platelets (33%), decreased estimated glomerular filtration rate (28%), increased aspartate aminotransferase (25%), decreased sodium (22%), increased magnesium (22%), increased potassium (21%), decreased calcium (21%), and increased alkaline phosphatase (20%).

References:

1. Pluvicto. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Oh SW, Cheon GJ. Prostate-specific membrane antigen PET imaging in prostate cancer: opportunities and challenges. *Korean J Radiol*. 2018;19(5):819-831. doi:10.3348/kjr.2018.19.5.819 **3.** Hofman MS, Violet J, Hicks RJ, et al. [^{177}Lu]-PSMA-617 radionuclide treatment in patients with metastatic castration-resistant prostate cancer (LuPSMA trial): a single-centre, single-arm, phase 2 study. *Lancet Oncol*. 2018;19(6):825-833. doi:10.1016/S1470-2045(18)30198-0 **4.** Vlachostergios PJ, Niaz MJ, Sun M, et al. Prostate-specific membrane antigen uptake and survival in metastatic castration-resistant prostate cancer. *Front Oncol*. 2021;11:630589. doi:10.3389/fonc.2021.630589 **5.** Benešová M, Schäfer M, Bauder-Wüst U, et al. Preclinical evaluation of a tailor-made DOTA-conjugated PSMA inhibitor with optimized linker moiety for imaging and endoradiotherapy of prostate cancer. *J Nucl Med*. 2015;56(6):914-920. doi:10.2967/jnumed.114.147413 **6.** Woythal N, Arsenic R, Kempkensteffen C, et al. Immunohistochemical validation of PSMA expression measured by ^{68}Ga-PSMA PET/CT in primary prostate cancer. *J Nucl Med*. 2018;59(2):238-243. doi:10.2967/ jnumed.117.195172 **7.** Hupe MC, Philippi C, Roth D, et al. Expression of prostate-specific membrane antigen (PSMA) on biopsies is an independent risk stratifier of prostate cancer patients at time of initial diagnosis. *Front Oncol*. 2018;8:623. doi:10.3389/fonc.2018.00623 **8.** Pomykala KL, Czernin J, Grogan TR, Armstrong WR, Williams J, Calais J. Total-body ^{68}Ga-PSMA-11 PET/CT for bone metastasis detection in prostate cancer patients: potential impact on bone scan guidelines. *J Nucl Med*. 2020;61(3):405-411. doi:10.2967/jnumed.119.230318 **9.** Wang L, Wang L, Wang X, Wu D. The evolving role of PSMA-PET/CT in prostate cancer management: an umbrella review of diagnostic restaging, therapeutic redirection, and survival impact; *Curr Oncol Rep*. 2025;27(6):774-787. doi:10.1007/s11912-025-01682-2 **10.** Morris MJ, Castellano D, Herrmann K, et al; PSMAfore Investigators. ^{177}Lu-PSMA-617 versus a change of androgen receptor pathway inhibitor therapy for taxane-naive patients with progressive metastatic castration-resistant prostate cancer (PSMAfore): a phase 3, randomised, controlled trial. *Lancet*. 2024;404(10459):1227-1239. doi:10.1016/S0140-6736(24)01653-2 **11.** Data on file. PLUVICTO PSMAddition trial. Novartis Pharmaceuticals Corp; June 2026. **12.** Sartor O, de Bono J, Chi KN, et al; VISION Investigators. Lutetium-177–PSMA-617 for metastatic castration-resistant prostate cancer. *N Engl J Med*. 2021;385(12)(protocol):1091-1103. doi:10.1056/NEJMoa2107322 **13.** Data on file. PLUVICTO NPS Metrics. Novartis Pharmaceuticals Corp; March 2026. **14.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.5.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed January 23, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. **15.** Ferdinandus J, Fendler WP, Farolfi A, et al. PSMA PET validates higher rates of metastatic disease for European Association of Urology biochemical recurrence risk groups: an international multicenter study. *J Nucl Med*. 2022;63(1):76-80. doi:10.2967/jnumed.121.262821 **16.** Pienta KJ, Gorin MA, Rowe SP, et al. A phase 2/3 prospective multicenter study of the diagnostic accuracy of prostate specific membrane antigen PET/CT with ^{18}F-DCFPyL in prostate cancer patients (OSPREY). *J Urol*. 2021;206(1):52-61. doi:10.1097/JU.0000000000001698 **17.** ClinicalTrials.gov. Gallium Ga 68-labeled PSMA-11 PET/CT in detecting recurrent prostate cancer in patients after initial therapy. https://clinicaltrials.gov/study/NCT02940262. Accessed June 24, 2026. **18.** Morris MJ, Rowe SP, Gorin MA, et al. Diagnostic performance of ^{18}F-DCFPyL-PET/CT in men with biochemically recurrent prostate cancer: results from the CONDOR phase III, multicenter study. *Clin Cancer Res*. 2021;27(13):3674-3682. doi:10.1158/1078-0432.CCR-20-4573 **19.** Unterrainer LM, Hope TA, Fendler WP, et al. Low- and high-volume disease in metastatic hormone-sensitive prostate cancer: from CHAARTED to PSMA PET—an international multicenter retrospective study. *J Nucl Med*. 2025;66(1):54-60. doi:10.2967/jnumed.124.268441

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IN METASTATIC PROSTATE CANCER,

UTILIZE EARLY PSMA-PET TESTING TO INFORM TREATMENT DECISIONS AND ASSESS PLUVICTO ELIGIBILITY

With more than 80% of patients with prostate cancer having PSMA+ disease, early PSMA-PET scans help with[7,8]:

- Improved staging and disease classification[15,16,18]
- Designing treatment plans[19]
- Ensuring patients receive PLUVICTO at the earliest eligible opportunity
  - **For patients with PSMA+ mAPMN/S PC (mHSPC):** PLUVICTO in combination with ARPI at any point after diagnosis[1,11]
  - **For patients with PSMA+ mAPMR PC (mCRPC):** PLUVICTO after progression on only 1 prior ARPI, received at any point in the prostate cancer journey[1,10,*]

LEARN MORE ABOUT HOW PLUVICTO MAY BE RIGHT FOR YOUR PATIENTS ACROSS THE CONTINUUM OF PSMA+ METASTATIC PROSTATE CANCER AT **PLUVICTO-HCP.COM**

*For patients considered appropriate to delay taxane-based chemotherapy.[1]

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