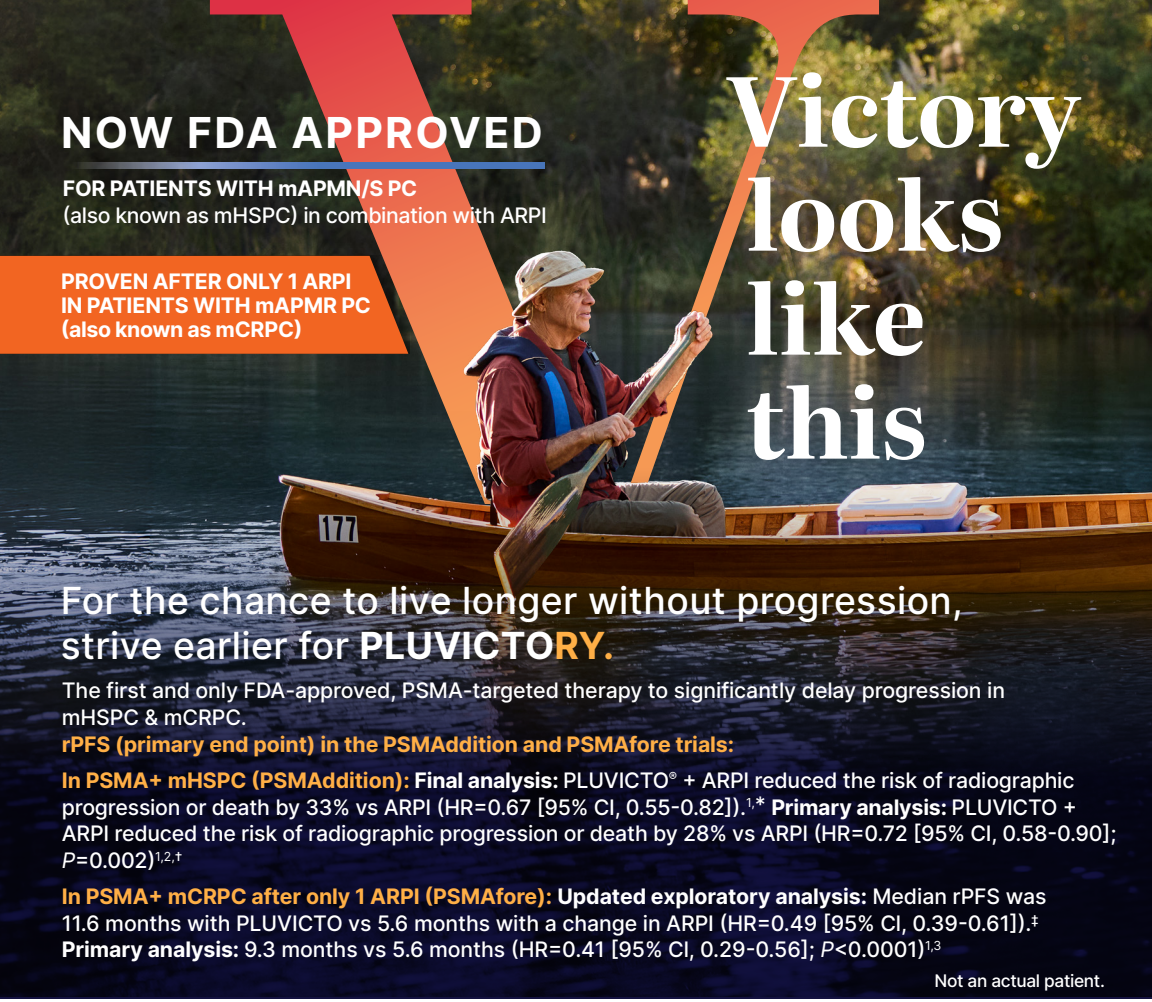


Indications

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.

ARPI, androgen receptor pathway inhibitor; HR, hazard ratio; 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; NE, not estimable; PSMA, prostate-specific membrane antigen; PSMA+, PSMA positive; rPFS, radiographic progression-free survival.

*Median rPFS was not reached in the PLUVICTO + ARPI arm vs 48.5 months (95% CI, 40.5-NE) in the ARPI arm. Final rPFS analysis was performed with a median follow-up period of 37.7 months vs the primary analysis at 23.6 months. This analysis was not controlled for Type-I error.[2,4]

†Median rPFS was not reached in either arm.[1]

‡Exploratory rPFS analysis was performed with a median follow-up period of 24 months vs the primary analysis at 7 months. This analysis was not controlled for Type-I error.[3]

Please see additional Important Safety Information throughout and on pages 11-12 and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

NOW FDA APPROVED FOR PATIENTS WITH mAPMN/S PC (mHSPC) in combination with ARPI

In PSMA+ mHSPC,

CHOOSE PLUVICTO AT THE **EARLIEST ELIGIBLE OPPORTUNITY**

mHSPC[1,4]

PLUVICTO

For patients with mHSPC (+ ARPI) at any point after diagnosis

	High volume	Low volume
De novo disease	✓	✓
Recurrent disease	✓	✓

IMPORTANT SAFETY INFORMATION (continued)

Risk From Radiation Exposure (continued)

- 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 11-12 and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

When treating mHSPC,

AIM FOR PLUVICTO EVEN EARLIER

AIM for a better treatment in mHSPC by adding a PSMA-targeted therapy to ARPI[1]

WITH APPROVAL IN AN EARLIER SETTING, HOW DO YOU SEE YOUR PRACTICE CHANGING?

HSPC, hormone-sensitive prostate cancer.

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.

Please see additional Important Safety Information throughout and on pages 11-12 and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

NOW FDA APPROVED FOR PATIENTS WITH mAPMN/S PC (mHSPC) in combination with ARPI

MEET PATIENTS WITH PSMA+ mHSPC WHO ARE ELIGIBLE FOR PLUVICTO

Plan for PLUVICTO in mHSPC: **Start PLUVICTO with ARPI after diagnosis**

Jeffrey wants to continue his Saturday shuffleboard games with his recreational league.

Jeffrey, 66 (high volume)

Diagnosed with high-volume mHSPC

- PSMA+ disease
- 6 bone metastases (2 lesions beyond the vertebral bodies and pelvis) and 3 lymph node metastases
- ECOG 1
- Gleason 9
- PSA: 51 ng/mL
- Mild-to-moderate, disease-related symptoms

Grant wants to continue teaching his grandson guitar on the weekends.

Grant, 68 (low volume)

Diagnosed with low-volume, de novo mHSPC

- PSMA+ disease
- 3 bone metastases and 4 lymph node metastases
- ECOG 0
- Gleason 8
- PSA: 19 ng/mL
- No prior prostate cancer treatment
- Mild disease-related symptoms

Hypothetical patient cases.

WHICH OF YOUR PATIENTS WITH PSMA+ mHSPC **COULD BENEFIT FROM PLUVICTO + ARPI NOW?**

ECOG, Eastern Cooperative Oncology Group; PSA, prostate-specific antigen.

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.

Please see additional Important Safety Information throughout and on pages 11-12 and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

NOW FDA APPROVED FOR PATIENTS WITH mAPMN/S PC (mHSPC) in combination with ARPI

LONGER LIFE WITHOUT PROGRESSION IS POSSIBLE WITH PLUVICTO. THAT'S VICTORY.

Primary end point

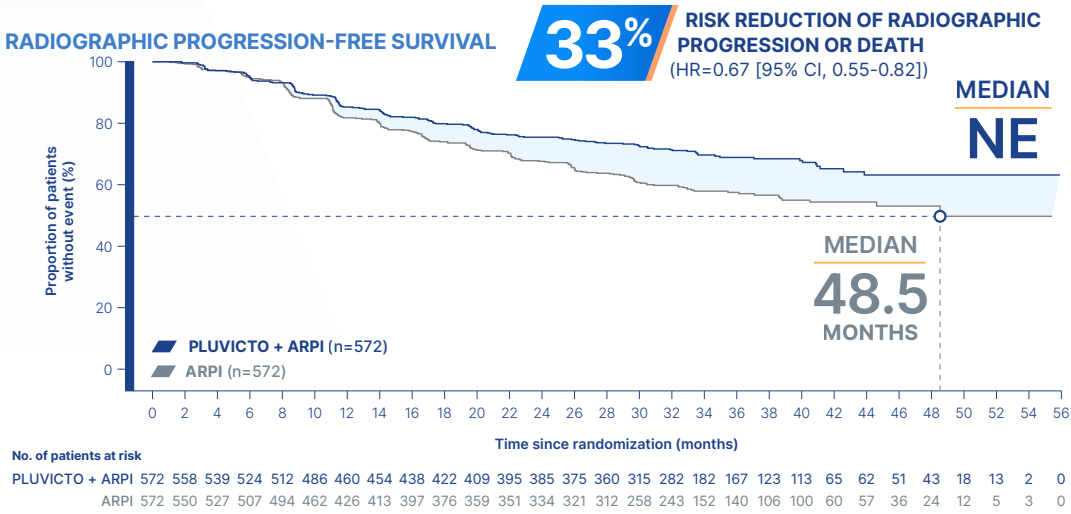
rPFS: In the primary analysis, PLUVICTO + ARPI significantly decreased the risk of radiographic progression or death vs ARPI[1]

- Median rPFS was not reached in either arm (HR=0.72 [95% CI, 0.58-0.90]; *P*=0.002)

In the final analysis

PLUVICTO + ARPI reduced the risk of radiographic progression or death[2]

- Median rPFS was not reached in the PLUVICTO + ARPI arm vs 48.5 months (95% CI, 40.5-NE) in the ARPI arm



No. of patients at risk

PLUVICTO + ARPI	572	558	539	524	512	486	460	454	438	422	409	395	385	375	360	315	282	182	167	123	113	65	62	51	43	18	13	2	0
ARPI	572	550	527	507	494	462	426	413	397	376	359	351	334	321	312	258	243	152	140	106	100	60	57	36	24	12	5	3	0

- Final rPFS analysis was performed with a median follow-up period of 37.7 months vs the primary analysis at 23.6 months. This analysis was not controlled for Type-I error[2,4]

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.

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.

Please see additional Important Safety Information throughout and on pages 11-12 and full Prescribing Information.

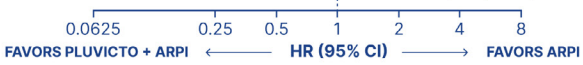
PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

PSMAddition: A study of PLUVICTO in mHSPC

rPFS BENEFIT WAS CONSISTENT ACROSS SUBGROUPS*

rPFS benefit was consistent across tumor volume or de novo or recurrent diagnosis[2,5]

		HR (95% CI)	Events, n/N (%) PLUVICTO + ARPI	Events, n/N (%) ARPI
All patients		0.67 (0.55, 0.82)	168/572 (29.4)	222/572 (38.8)
Tumor volume	High	0.69 (0.55, 0.86)	139/389 (35.7)	177/390 (45.4)
	Low	0.61 (0.38, 0.97)	29/183 (15.8)	45/182 (24.7)
Initial Gleason score	<8	0.63 (0.41, 0.98)	36/153 (23.5)	45/133 (33.8)
	≥8	0.68 (0.53, 0.86)	118/388 (30.4)	163/407 (40.0)
Age	<70 years	0.68 (0.52, 0.89)	96/326 (29.4)	124/326 (38.0)
	≥70 years	0.66 (0.49, 0.90)	72/246 (29.3)	98/246 (39.8)
ECOG performance status	0	0.73 (0.57, 0.94)	109/397 (27.5)	137/407 (33.7)
	1-2	0.54 (0.38, 0.75)	59/175 (33.7)	84/162 (51.9)
Baseline PSA level	<Median	0.80 (0.60, 1.05)	90/279 (32.3)	109/287 (38.0)
	≥Median	0.56 (0.42, 0.75)	76/284 (26.8)	113/283 (39.9)
Baseline LDH level	≤260 IU/L	0.64 (0.51, 0.80)	130/471 (27.6)	190/489 (38.9)
	>260 IU/L	0.59 (0.30, 1.19)	21/37 (56.8)	18/33 (54.5)
Previous/planned treatment to primary tumor	Yes	0.70 (0.46, 1.06)	40/156 (25.6)	51/155 (32.9)
	No	0.66 (0.53, 0.84)	128/416 (30.8)	171/417 (41.0)
mHSPC[a]	De novo	0.67 (0.51, 0.88)	92/298 (30.9)	115/274 (42.0)
	Recurrent	0.71 (0.52, 0.96)	70/249 (28.1)	99/274 (36.1)



LDH, lactate dehydrogenase.

*Subgroup analyses are exploratory and not powered for statistical significance.[2]

[a]Not a prespecified patient population and analyzed separately from other subgroup data. De novo included stage IVb at diagnosis. Recurrent included stages IVa, IV, and below IV at diagnosis.[4]

IMPORTANT SAFETY INFORMATION (continued)

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%).

Please see additional Important Safety Information throughout and on pages 11-12 and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

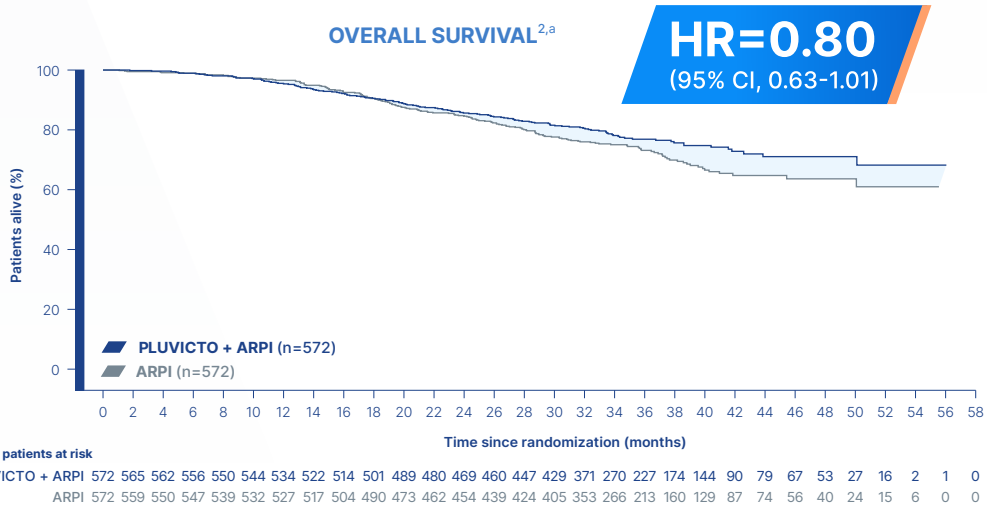
PSMAddition: A study of PLUVICTO in mHSPC

OVERALL SURVIVAL ANALYSIS IN THE PSMAddition TRIAL

Key secondary end point

OS: Numerically favored PLUVICTO

- OS data were still maturing, and statistical significance was not reached at interim analysis 2 (IA2)
- HR was **0.84 (95% CI, 0.63-1.13)** at IA1 (median follow-up of 23.6 months)[4,*]
- HR decreased to **0.80 (95% CI, 0.63-1.01)** at IA2 (median follow-up of 37.7 months)[†]
- Median OS was not reached in either arm[2,4]



No. of patients at risk

PLUVICTO + ARPI	572	565	562	556	550	544	534	522	514	501	489	480	469	460	447	429	371	270	227	174	144	90	79	67	53	27	16	2	1	0
ARPI	572	559	550	547	539	532	527	517	504	490	473	462	454	439	424	405	353	266	213	160	129	87	74	56	40	24	15	6	0	0

IA1, interim analysis 1.

[a]Data are from the second interim analysis.
*Data cutoff for IA1 was January 13, 2025, with a total of 184 events occurring across both study arms; 16% of patients randomized to the ARPI arm subsequently crossed over to receive PLUVICTO following confirmed radiographic progression.[4]
[†]Data cutoff for IA2 was March 17, 2026, with a total of 291 events occurring across both study arms. Data are from an unadjusted OS analysis that did not account for crossover; 21% of patients randomized to the ARPI arm subsequently crossed over to receive PLUVICTO following confirmed radiographic progression.[2]

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout and on pages 11-12 and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

PSMAddition: A study of PLUVICTO in mHSPC

ADDITIONAL END POINTS

Nearly 9 out of 10 patients treated with PLUVICTO + ARPI achieved undetectable PSA*

PSA nadir <0.2 ng/mL at 48 weeks[2]:

More patients achieved undetectable PSA with PLUVICTO + ARPI vs ARPI†

87.4% with PLUVICTO + ARPI

(n/N=320/366; 95% CI, 83.6-90.6)

vs

75% with ARPI

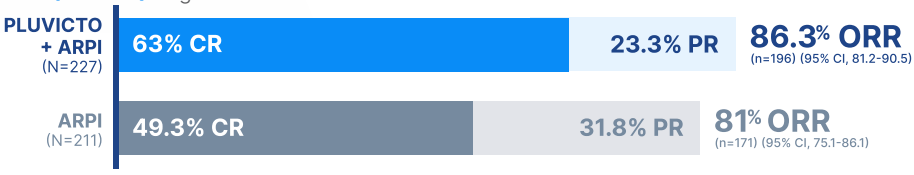
(n/N=294/392; 95% CI, 70.4-79.2)

*PSA nadir (<0.2 ng/mL).

6 in 10 patients achieved complete responses with PLUVICTO + ARPI†

In the final analysis

ORR (CR + PR): Higher ORR achieved with PLUVICTO + ARPI vs ARPI[2,‡]



Responses are based on soft tissue and bone lesion assessment.

†Not powered for statistical significance.

‡By BICR per PCWG3-modified RECIST v1.1 criteria.

- Median DOR was not reached with PLUVICTO + ARPI (95% CI, NR-NR) vs 42.55 with ARPI (95% CI, 33.12-NR)[5]

BICR, Blinded Independent Central Review; NR, not reached; PCWG3, Prostate Cancer Working Group 3; RECIST, Response Evaluation Criteria in Solid Tumors.

Overall response rate (ORR) is the percentage of patients who had a complete response (CR) or partial response (PR) at any point after the start of the study treatment until the end of treatment.[6]

CR is the disappearance of all target lesions. Any pathological lymph nodes (target or nontarget) must have reduction in short axis to <10 mm.[6]

PR is at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.[6]

IMPORTANT SAFETY INFORMATION (continued)

Risk From Radiation Exposure (continued)

- Ensure patients increase oral fluid intake and advise them to void as often as possible to reduce bladder radiation.

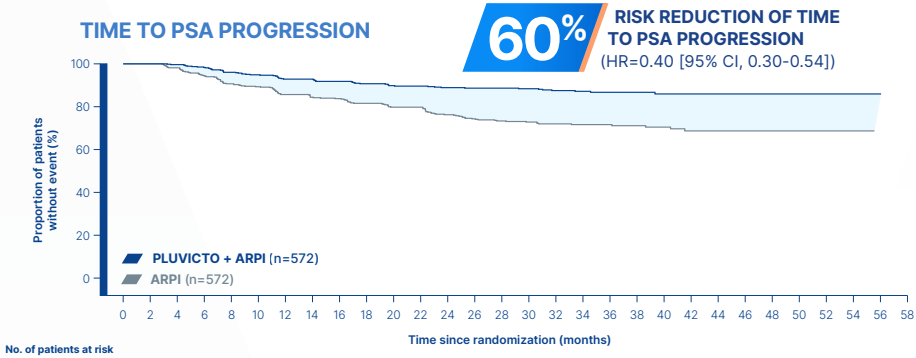
Please see additional Important Safety Information throughout and on pages 11-12 and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

ADDITIONAL END POINTS (continued)

60% risk reduction in time to PSA progression with PLUVICTO + ARPI vs ARPI*

Time to PSA progression: Median time to PSA progression was not reached with PLUVICTO + ARPI (NE-NE) vs not reached with ARPI (NE-NE)[2]

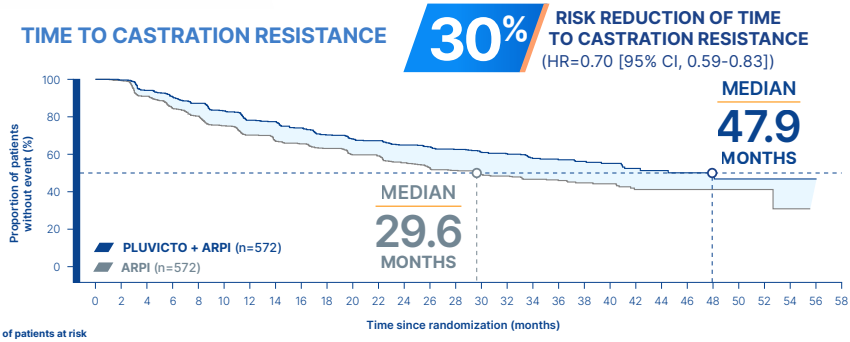


No. of patients at risk

PLUVICTO + ARPI	572	555	542	524	501	475	448	444	425	410	397	390	370	356	346	333	278	204	177	130	98	68	61	50	29	18	12	2	1	0
ARPI	572	548	524	495	465	446	414	398	383	364	349	342	320	307	288	279	234	163	144	108	90	63	53	36	17	12	10	3	0	0

Progression to mAPMR PC (mCRPC) was delayed for longer with PLUVICTO + ARPI vs ARPI*

Time to castration resistance: Median time to castration resistance was 47.9 months with PLUVICTO + ARPI (40.9-NE) vs 29.6 months with ARPI (25.3-36.6)[2,†]



No. of patients at risk

PLUVICTO + ARPI	572	559	523	499	478	449	420	415	396	371	356	351	334	326	311	293	248	175	153	113	91	49	43	37	30	14	11	2	1	0
ARPI	572	553	502	462	436	408	379	358	349	334	315	307	284	270	262	247	210	149	130	93	86	52	49	34	20	12	9	2	0	0

*Not powered for statistical significance.
†Time to castration resistance events included rise in serum PSA levels, progression of pre-existing disease, and appearance of new metastases.[4]

IMPORTANT SAFETY INFORMATION (continued)

Risk From Radiation Exposure (continued)

- 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 11-12 and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

PLUVICTO DEMONSTRATED A PREDICTABLE SAFETY PROFILE

ARs of grades ≥3 occurred at similar rates between study arms[4]

- Incidence of grade ≥3 TEARs: 50.7% (n=286) with PLUVICTO + ARPI vs 43% (n=243) with ARPI

ADVERSE REACTIONS OCCURRING AT ≥10% INCIDENCE IN PATIENTS WHO RECEIVED PLUVICTO IN COMBINATION WITH ARPI OR ARPI IN PSMAddition[1]

	PLUVICTO + ARPI (n=564)		ARPI (n=565)	
Adverse reactions	All grades (%)	Grades 3 or 4 (%)	All grades (%)	Grades 3 or 4 (%)
General disorders				
Fatigue[a]	51	1.4	41	1.8
Decreased appetite	14	0.9	7	0.2
Gastrointestinal disorders				
Dry mouth[a]	46	0	3.7	0
Nausea	34	0.2	9	0
Constipation	18	0	16	0
Vomiting[a]	14	0.7	3.7	0
Diarrhea	12	0.2	10	0
Nervous system disorders				
Dysgeusia[a]	13	0	4.1	0
Headache	12	0	9	0.4

[a]Includes multiple similar terms.

- PLUVICTO was permanently discontinued due to adverse reactions in 8% of patients who received PLUVICTO in combination with ARPI[1]
- Clinically relevant adverse reactions in <10% of patients who received PLUVICTO in combination with ARPI included abdominal pain, dizziness, acute kidney injury, dry eye, dry skin, stomatitis, gastroesophageal reflux disease, vertigo, eye irritation, oral fungal infection, dysphagia, and esophagitis[1]

AR, adverse reaction; TEAR, treatment-emergent adverse reaction.

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.

Please see additional Important Safety Information throughout and on pages 11-12 and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

INDICATIONS AND IMPORTANT SAFETY INFORMATION

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.

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.

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.

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.

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.

Please see additional Important Safety Information on the following page and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

IMPORTANT SAFETY INFORMATION (continued)

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%).

Please see full Prescribing Information.

PSMAddition trial design: PSMAddition was an open-label, multicenter, randomized, phase 3 clinical trial evaluating PLUVICTO + ARPI in 1144 adult patients with PSMA+ mAPMN/S PC (mHSPC). Participants were randomized in a 1:1 ratio to receive PLUVICTO (7.4 GBq every 6 weeks for 6 cycles) + ARPI or ARPI. Patients received a gonadotropin-releasing hormone (GnRH) agonist or antagonist concurrently or had a bilateral orchiectomy. The primary end point was rPFS. Key secondary end point: OS; select additional end points: undetectable PSA,* ORR, time to PSA progression, time to castration resistance.[1,4]

GBq, gigabecquerel.
*PSA nadir (<0.2 ng/mL).

PSMAfore trial design: PSMAfore was an open-label, multicenter, randomized, phase 3 clinical trial evaluating PLUVICTO in 468 adult taxane-naive patients with PSMA+ mAPMR PC (mCRPC) previously treated with 1 ARPI, who were considered appropriate to delay taxane-based chemotherapy. Participants were randomized in a 1:1 ratio to receive PLUVICTO (7.4 GBq every 6 weeks for 6 cycles) or a change in ARPI. The primary end point was rPFS.[1,3]

References: 1. Pluvicto. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Data on file. PLUVICTO PSMAddition final analysis. Novartis Pharmaceuticals Corp; June 2026. **3.** 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. **4.** Data on file. PLUVICTO PSMAddition trial. Novartis Pharmaceuticals Corp; June 2026. **5.** Data on file. PLUVICTO PSMAddition final analysis 2. Novartis Pharmaceuticals Corp; June 2026. **6.** Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). *Eur J Cancer*. 2009;45(2):228-247. doi:10.1016/j.ejca.2008.10.026 **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 68Ga-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.** Data on file. PLUVICTO NPS Metrics. Novartis Pharmaceuticals Corp; June 2025.

Explore PLUVICTO clinical resources >

Practical tools and guidance to support your patients across testing, initiation, administration, and monitoring

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

NOW FDA APPROVED FOR PATIENTS WITH mAPMN/S PC (mHSPC) in combination with ARPI

For your patients with mHSPC,

For the chance to live longer without progression, strive earlier for **PLUVICTORY.**

PLUVICTO targets PSMA, a biomarker overexpressed in more than 80% of men with prostate cancer[1,7,8]

In PSMA+ mHSPC (PSMAddition),

Final analysis: PLUVICTO + ARPI **reduced the risk of radiographic progression or death by 33%** vs ARPI (HR=0.67 [95% CI, 0.55-0.82])[1,2,*]

PLUVICTO demonstrated a **predictable safety profile**

- ARs of grades ≥3 occurred at similar rates between study arms[1]
  - Incidence of grade ≥3 TEARs: 50.7% (n=286) with PLUVICTO + ARPI vs 43% (n=243) with ARPI[4]
- Most common (≥20%) ARs in PSMA+ mHSPC: Fatigue, dry mouth, and nausea[1]

PLUVICTO can be delivered within 5 days of order placement,[†] so your patients can be treated as soon as possible[9]

*Final rPFS analysis was performed with a median follow-up period of 37.7 months vs the primary analysis at 23.6 months. This analysis was not controlled for Type-I error.[2,4]

[†]Exceptions may apply for syringe form and select geographic locations.[9]

AIM FOR MORE TIME WITHOUT PROGRESSION: CHOOSE PLUVICTO + ARPI IN mHSPC[1]

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.

Please see additional Important Safety Information throughout and on pages 11-12 and full Prescribing Information.

NOVARTIS

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

6/26

FA-11648247