WHEN TREATING mAPMR PC (also known as mCRPC)

Change your next conversation.

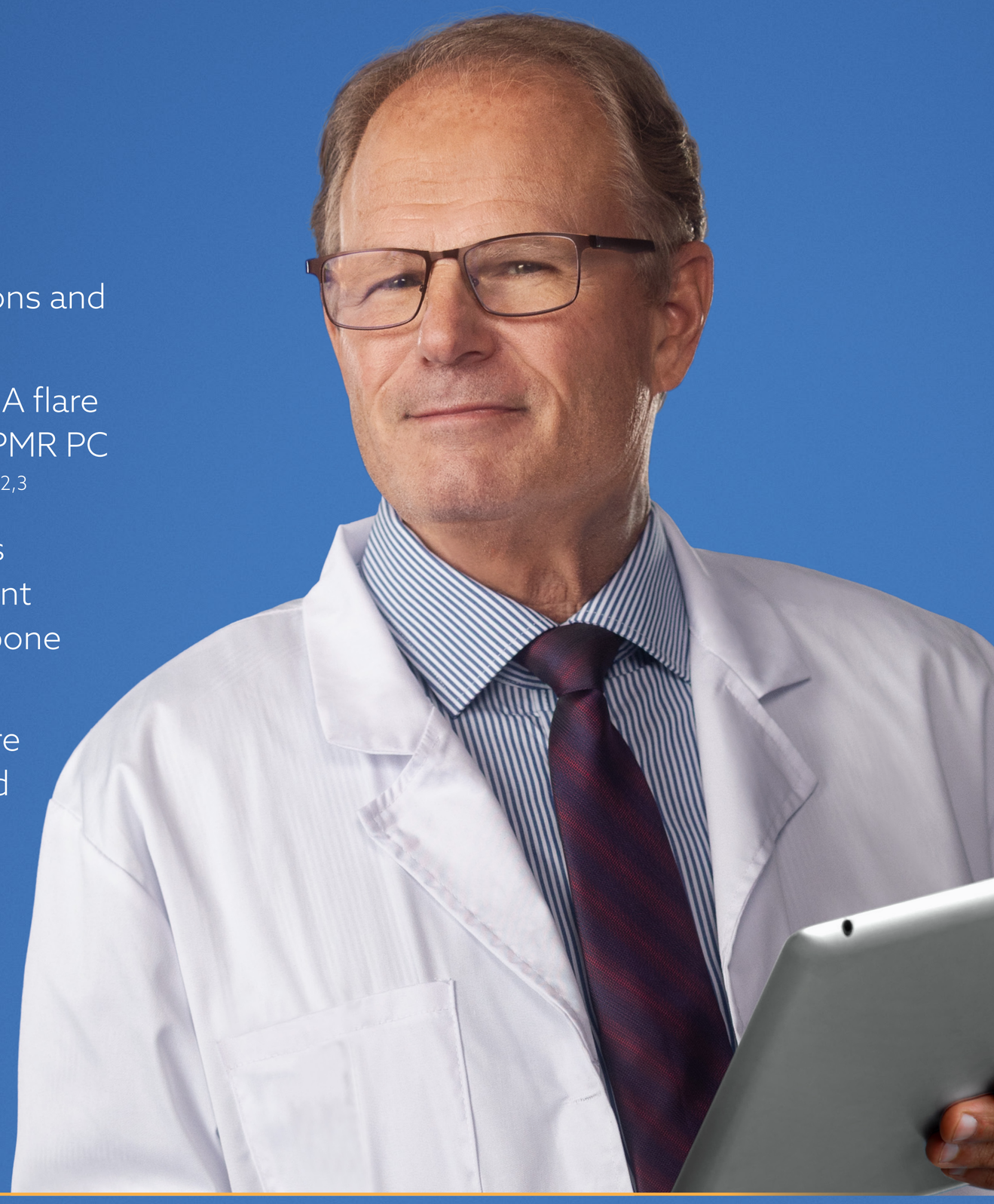
Sharing with a patient that their cancer has spread tells a difficult story.

The power of targeted medicine is that it can change the conversation from delivering bad news to the hope for more time.

Not an actual patient, care partner, or health care professional.

More than 80% of patients with prostate cancer have PSMA+ disease.[1]

PSMA-PET/CT scans can detect PSMA+ lesions.[2]



Routine CT and bone scans are essential for comprehensive assessment.[3]

PSMA-PET/CT scans are used to visualize PSMA+ lesions and can unlock targeted treatment options for patients.[2]

PSMA-PET/CT may miss PSMA-negative disease. PSMA flare (increased or occasionally decreased uptake after mAPMR PC (mCRPC) therapies) can confound scan interpretation.[2,3]

- In the VISION and PSMAfore trials, PSMA-PET/CT was used only at baseline and not during or after treatment cycles to determine response to treatment. CT and bone scans were used to monitor progression[4,5]
- PSMA-PET tumor reduction is not a validated measure of outcomes like rPFS or OS. Clinical decisions should prioritize validated end points over PSMA-PET results
- The recommended PLUVICTO dosage is 7.4 GBq intravenously every 6 weeks for 6 doses, or until disease progression or unacceptable toxicity[6]

CT, computed tomography; GBq, gigabecquerel; mCRPC, metastatic castration-resistant prostate cancer; OS, overall survival; PET, positron emission tomography; PSMA, prostate-specific membrane antigen; PSMA+, PSMA positive; rPFS, radiographic progression-free survival.

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.

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INITIAL PET SCAN
11/2017

PET SCAN AFTER 4 CYCLES
5/2018

Individual patient results will vary.

73-YEAR-OLD PSMA+ mAPMR PC (mCRPC) PATIENT, POST-ARPI, POST-TAXANE[7]

The PSMA-PET scans depicted above are from a real patient who received both an initial scan required to qualify for treatment and a follow-up scan. In the VISION and PSMAfore trials, PSMA-PET scans were only used at baseline and were not performed during or after treatment cycles for response evaluation. PSMA-PET tumor reduction is not a validated measure of long-term outcomes like rPFS or OS. This patient is not from the VISION or PSMAfore clinical trial. Therapies given during mCRPC treatment may confound the results of PSMA-PET scans. Please follow your institution's guidelines when making monitoring decisions.[1,4,5,7]

ARPI, androgen receptor pathway inhibitor.

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Every choice is a chance to change the conversation.

When we met our current doctor, he said, 'I think I can help you,' and that's when I learned about PLUVICTO®.

-Actual post-ARPI, post-taxane PSMA+ mAPMR PC (mCRPC) patient



Not an actual patient or care partner.

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.

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%),

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Discuss how a targeted option could evolve the story.

VISION was a pivotal trial in PSMA+ mAPMR PC (mCRPC) in the post-ARPI, post-chemotherapy setting[6]

Median OS (alternate primary end point): 15.3 months with PLUVICTO + BSOC (n/N=343/551) vs 11.3 months with BSOC alone (n/N=187/280) (HR=0.62 [95% CI, 0.52-0.74]; *P*<0.001)[6,8]

Median rPFS (alternate primary end point): 8.7 months with PLUVICTO + BSOC (n/N=254/385) vs 3.4 months with BSOC alone (n/N=93/196) (HR=0.40 [95% CI, 0.31-0.52]; *P*<0.001)[8,9]

- Interpretation of the magnitude of the rPFS effect was limited due to a high degree of censoring from early dropout in the control arm

Response data (secondary end points):

- ORR: 49% with PLUVICTO + BSOC (n/N=91/184; 95% CI, 42-57) vs 1.6% with BSOC alone (n/N=1/64; 95% CI, 0-8)[6,10,†,‡]
  - CR was 9% with PLUVICTO + BSOC vs 0% with BSOC alone
  - PR was 40% with PLUVICTO + BSOC vs 1.6% with BSOC alone
- PSA response: 46% with PLUVICTO + BSOC (n/N=177/385) vs 7.1% with BSOC alone (n/N=14/196)[5,10,§]

Safety profile:

- In the VISION trial, most common ARs (≥20%) in patients who received PLUVICTO + BSOC were fatigue, dry mouth, nausea, back pain, arthralgia, decreased appetite, and constipation[6]

VISION trial design: VISION was an international, prospective, open-label, multicenter, randomized phase 3 clinical trial evaluating PLUVICTO in 831 adult patients. Select inclusion criteria: The study included patients with PSMA+ mCRPC (at least 1 PSMA+ lesion with gallium Ga 68 gozetotide uptake greater than normal liver) previously treated with at least 1 ARPI and 1 or 2 taxane regimens. Participants were randomized in a 2:1 ratio to receive PLUVICTO (7.4 GBq every 6 weeks for up to 6 cycles) + protocol-permitted BSOC or BSOC alone. Alternate primary end points included OS and rPFS. PSMA-PET scans were not part of the patient response evaluation protocol.[6,8]

AR, adverse reaction; BSOC, best standard of care; CR, complete response; HR, hazard ratio; ORR, overall response rate; PR, partial response; PSA, prostate-specific antigen.

*For patients considered appropriate to delay taxane-based chemotherapy.[6]

†Responses are based on soft tissue assessment and bone lesion progression for patients with measurable disease at baseline.[6]

‡Stratified Wald's Chi-square test 2-sided *P* value.[6]

§Odds ratio: 11.19 (95% CI, 6.25-20.04).[5,10]

IMPORTANT SAFETY INFORMATION (continued)

Myelosuppression (continued)

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.

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More time without progression for the days that matter most.

PSMAfore was a trial in PSMA+ mAPMR PC (mCRPC) post-ARPI without prior mCRPC chemotherapy[6]

rPFS: Primary end point

In the primary analysis, PLUVICTO achieved statistically significant rPFS[6]

- **Median rPFS was 9.3 months with PLUVICTO (n/N=60/233) vs 5.6 months with a change in ARPI (n/N=106/234) (HR=0.41 [95% CI, 0.29-0.56]; *P*<0.0001)**
- 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-1 error[4]

In the updated exploratory analysis, PLUVICTO more than doubled median rPFS vs a change in ARPI[4]

Median rPFS

11.6 MONTHS with PLUVICTO **vs** **5.6** MONTHS with a change in ARPI

HR=0.49 (95% CI, 0.39-0.61)

OS: Key secondary end point

Numerically favored PLUVICTO but was not statistically significant; high crossover rate may have confounded OS analysis[4,6]

- **60.3%** of patients randomized to the change in ARPI arm subsequently crossed over to receive PLUVICTO following confirmed radiographic progression[11]
- At the preplanned final analysis,* **HR=0.91** (95% CI, 0.72-1.14); median OS was 24.5 months with PLUVICTO and 23.1 months with a change in ARPI[6]

*Data cutoff for the final analysis was January 1, 2025, with a total of 299 events occurring.[11]

IMPORTANT SAFETY INFORMATION (continued)

Renal Toxicity (continued)

- 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.

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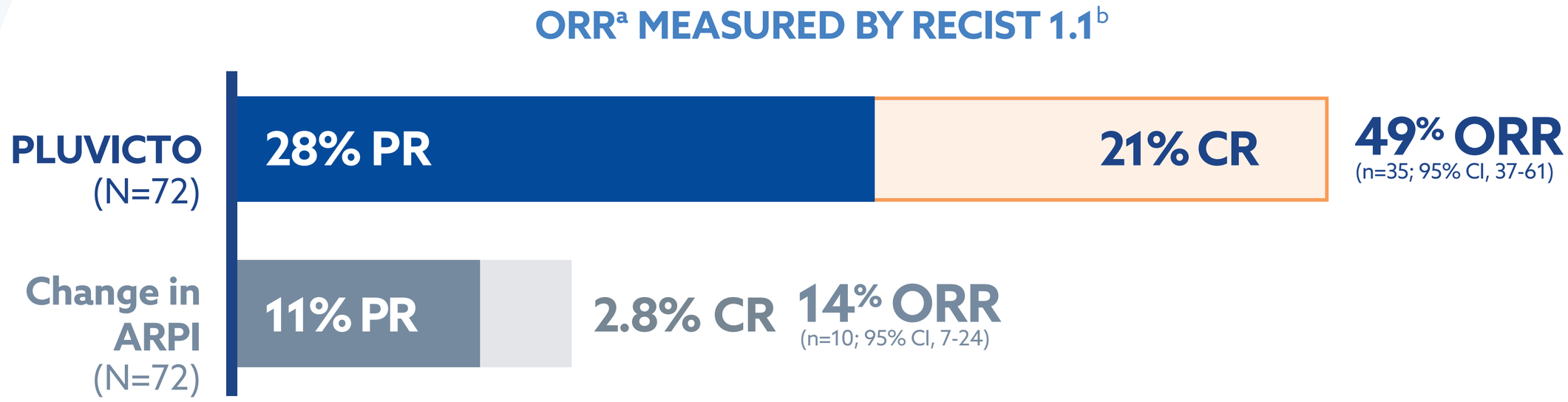
FDA APPROVED FOR PATIENTS WITHOUT PRIOR CHEMOTHERAPY

In PSMAfore,

Half of patients treated with PLUVICTO achieved a response.[6]

Additional end points

ORR: More patients had a response to PLUVICTO, with >7x more complete responses seen with PLUVICTO vs a change in ARPI[6,*]



ORR=CR+PR.
[a]Responses are based on soft tissue and bone lesion assessment.
[b]Patients with measurable disease at baseline.

PSA: More patients had a PSA decline with PLUVICTO: 51% (n/N=110/217; 95% CI, 44-58) vs 17% with a change in ARPI (n/N=39/225; 95% CI, 13-23)[4,*]

- Data are from patients with available PSA measurements at the time of the third data cutoff
- PSA50 response was defined as a confirmed decrease of 50% or greater

PSMAfore trial design: PSMAfore was an open-label, multicenter, randomized phase 3 clinical trial evaluating PLUVICTO in 468 adult patients. Select inclusion criteria: The study included taxane-naive patients with PSMA+ mAPMR PC (mCRPC) (at least 1 PSMA+ lesion [soft tissue or bone] with gallium Ga 68 gozetotide uptake greater than normal liver) 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. PSMA-PET scans were not part of the patient response evaluation protocol.[4,6]

RECIST, Response Evaluation Criteria in Solid Tumors.
*Not powered for statistical significance.

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.

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%).

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A treatment patients can tolerate is one they can complete.



The median number of doses of PLUVICTO in the PSMAfore trial (pre-chemotherapy) was 6.[6]

- 63% of patients received 6 doses[12]

Not an actual patient or care partner.

Please see Important Safety Information throughout and on pages 10-11 and full Prescribing Information.

PLUVICTO has a favorable safety profile

Grade ≥3 AE rates were lower in the PLUVICTO group with a longer median duration of exposure[4]

- Incidence of grade ≥3 TEAEs: 36% with PLUVICTO (n=81) vs 48% with a change in ARPI (n=112)[4]
- Median duration of exposure: 8.4 months with PLUVICTO vs 6.5 months with a change in ARPI[4]

PSMAfore: ADVERSE REACTIONS OCCURRING AT ≥10% INCIDENCE IN PATIENTS WHO RECEIVED PLUVICTO OR CHANGE IN ARPI[6,a]

	PLUVICTO (n=227)		Change in ARPI (n=232)	
Adverse reactions	All grades (%)	Grades 3 or 4 (%)	All grades (%)	Grades 3 or 4 (%)
Gastrointestinal disorders				
Dry mouth[b]	61	0.9	2.6	0
Nausea	32	0	12	0.4
Constipation	22	0.4	14	0
Diarrhea	17	0	9	0.4
Vomiting	11	0	4.7	0
General disorders				
Fatigue[b]	53	1.3	53	5
Metabolism and nutrition disorders				
Decreased appetite	22	0	19	0.4
Musculoskeletal and connective tissue disorders				
Arthralgia	20	0	23	0.4
Back pain	14	1.3	20	2.6

[a]National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 5.0.[13]

[b]Includes multiple similar terms.[6]

- Clinically relevant ARs in <10% of patients who received PLUVICTO included abdominal pain, dysgeusia, peripheral edema, headache, acute kidney injury, weight decreased, dry eye, urinary tract infection, dizziness, dry skin, oral fungal infection, gastroesophageal reflux disease, pyrexia, vertigo, stomatitis, dysphagia, esophagitis, pancytopenia, and bone marrow failure[6]

AE, adverse event; TEAE, treatment-emergent adverse event.

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Laboratory abnormalities

SELECT LABORATORY ABNORMALITIES (≥10%) THAT WORSENED FROM BASELINE IN PATIENTS WITH PSMA-POSITIVE mAPMR PC (mCRPC) WHO RECEIVED PLUVICTO OR CHANGE IN ARPI (BETWEEN-ARM DIFFERENCE OF ≥5% ALL GRADES) IN PSMAfore[6]

	PLUVICTO[a]		ARPI[b]	
Laboratory abnormalities	All grades (%)	Grades 3 or 4 (%)	All grades (%)	Grades 3 or 4 (%)
Hematology				
Decreased lymphocytes	78	27	57	12
Decreased hemoglobin	67	7[c]	50	7[c]
Decreased neutrophils	38	3.5	18	1.3
Decreased platelets	30	2.7	11	1.7
Chemistry				
Decreased eGFR[d]	41	0.9[c]	42	3
Increased alkaline phosphatase	31	8	50	10[c]
Increased magnesium	19	0.9[c]	28	0[c]
Decreased calcium	18	0.9	11	0.9
Decreased sodium	11	0[c]	18	0[c]
Decreased potassium	6	0.9[c]	18	2.6

eGFR, estimated glomerular filtration rate.

[a]The denominator used to calculate the rate for each laboratory parameter was based on 226 patients with a baseline value and at least one posttreatment value.[6]

[b]The denominator used to calculate the rate for each laboratory parameter varied from 231 to 232 based on the number of patients with a baseline value and at least one posttreatment value.[6]

[c]No grade 4 laboratory abnormalities worsening from baseline were reported.[6]

[d]"All grades" column represents patients having any worsened eGFR category of <90 mL/min/1.73 m^2 and "grade 3 or 4" column represents patients having any worsened eGFR category of <30 mL/min/1.73 m^2 calculated using the CKD-EPI formula.[6]

PLUVICTO has proven tolerability[4,6]

- **Permanent discontinuation rate due to an AE:** 6% with PLUVICTO (n=13) vs 5% with a change in ARPI (n=12)[4,6]
  - ARs leading to permanent discontinuation of PLUVICTO in ≥1% of patients who received PLUVICTO were thrombocytopenia (1.8%) and dry mouth (1.3%)[6]
- **Dose modification due to an AE:** 4% with PLUVICTO (n=8) vs 16% with a change in ARPI (n=36)[4]
  - The most frequent (≥0.5%) AR leading to a dose reduction of PLUVICTO in patients who received PLUVICTO was dry mouth (0.9%)[6]
- **Dose interruption due to an AE:** 12% with PLUVICTO (n=28) vs 19% with a change in ARPI (n=45)[4]
  - The most frequent (≥1%) ARs leading to a dose interruption of PLUVICTO in patients who received PLUVICTO were COVID-19 (3.1%) and anemia (1.8%)[6]

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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

Please see additional Important Safety Information on next page.

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Important Safety Information (continued)

within the range where PLUVICTO may cause temporary or permanent infertility.

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.

References: 1. Uemura M, Watabe T, Hoshi S, Tanji R, Yaginuma K, Kojima Y. The current status of prostate cancer treatment and PSMA theranostics. *Ther Adv Med Oncol*. 2023. doi:10.1177/17588359231182293 **2.** Locametz. Prescribing information. Novartis Pharmaceuticals Corp. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.1.2026. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed August 29, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. **4.** 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 **5.** 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 **6.** Pluvicto. Prescribing information. Novartis Pharmaceuticals Corp. **7.** Ventura D, Rassek P, Schindler P, et al. Early treatment response assessment with [^{177}Lu]PSMA whole-body-scintigraphy compared to interim PSMA-PET. *Cancer Imaging*. 2024;24(1):126. doi:10.1186/s40644-024-00773-w **8.** 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):1091-1103. doi:10.1056/NEJMoa2107322 **9.** Data on file. VISION [PSMA-617-01] study. Novartis Pharmaceuticals Corp; 2024. **10.** 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)(suppl):1091-1103. doi:10.1056/NEJMoa2107322 **11.** Fizazi K, Chi KN, Shore ND, et al. Final overall survival and safety analyses of the phase 3 PSMAfore trial of [^{177}Lu]Lu-PSMA-617 versus change of androgen receptor pathway inhibitor in taxane-naive patients with metastatic castration-resistant prostate cancer. *Ann Oncol*. 2025. doi:10.1016/j.annonc.2025.07.003 **12.** 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)(suppl 1):1227-1239. doi:10.1016/S0140-6736(24)01653-2 **13.** 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)(suppl 2):1227-1239. doi:10.1016/S0140-6736(24)01653-2

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Discuss what's possible with PLUVICTO.

The PSMAfore results lay the foundation for new conversations between physicians and patients.

PLUVICTO more than doubled median rPFS vs a change in ARPI[4]

- Updated exploratory analysis: Median rPFS was 11.6 months with PLUVICTO vs 5.6 months with a change in ARPI (HR=0.49 [95% CI, 0.39-0.61])*

OS numerically favored PLUVICTO but was not statistically significant; high crossover rate (60.3%) may have confounded OS analysis[4,6]

- At the preplanned final analysis,† HR=0.91 (95% CI, 0.72-1.14); median OS was 24.5 months with PLUVICTO and 23.1 months with a change in ARPI[6]

PLUVICTO demonstrated 7x more complete responses vs a change in ARPI[6,‡]

- 49% ORR with PLUVICTO (n=35; 95% CI, 37-61) vs 14% with a change in ARPI (n=10; 95% CI, 7-24)
- 21% CR and 28% PR with PLUVICTO vs 2.8% CR and 11% PR with a change in ARPI

PLUVICTO has a favorable safety profile and proven tolerability[4,6]

- Grade ≥3 AE rates were lower in the PLUVICTO group with a longer median duration of exposure[4]
- 6% permanent discontinuation rate due to an AE; 4% had a dose modification due to an AE; 12% had a dose interruption due to an AE[4,6]

*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.[4]
†Data cutoff for the final analysis was January 1, 2025, with a total of 299 events occurring.[11]
‡Not powered for statistical significance.

Indications

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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 Important Safety Information throughout and on pages 10-11 and full Prescribing Information.

NOVARTIS

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

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