

WHEN TREATING 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

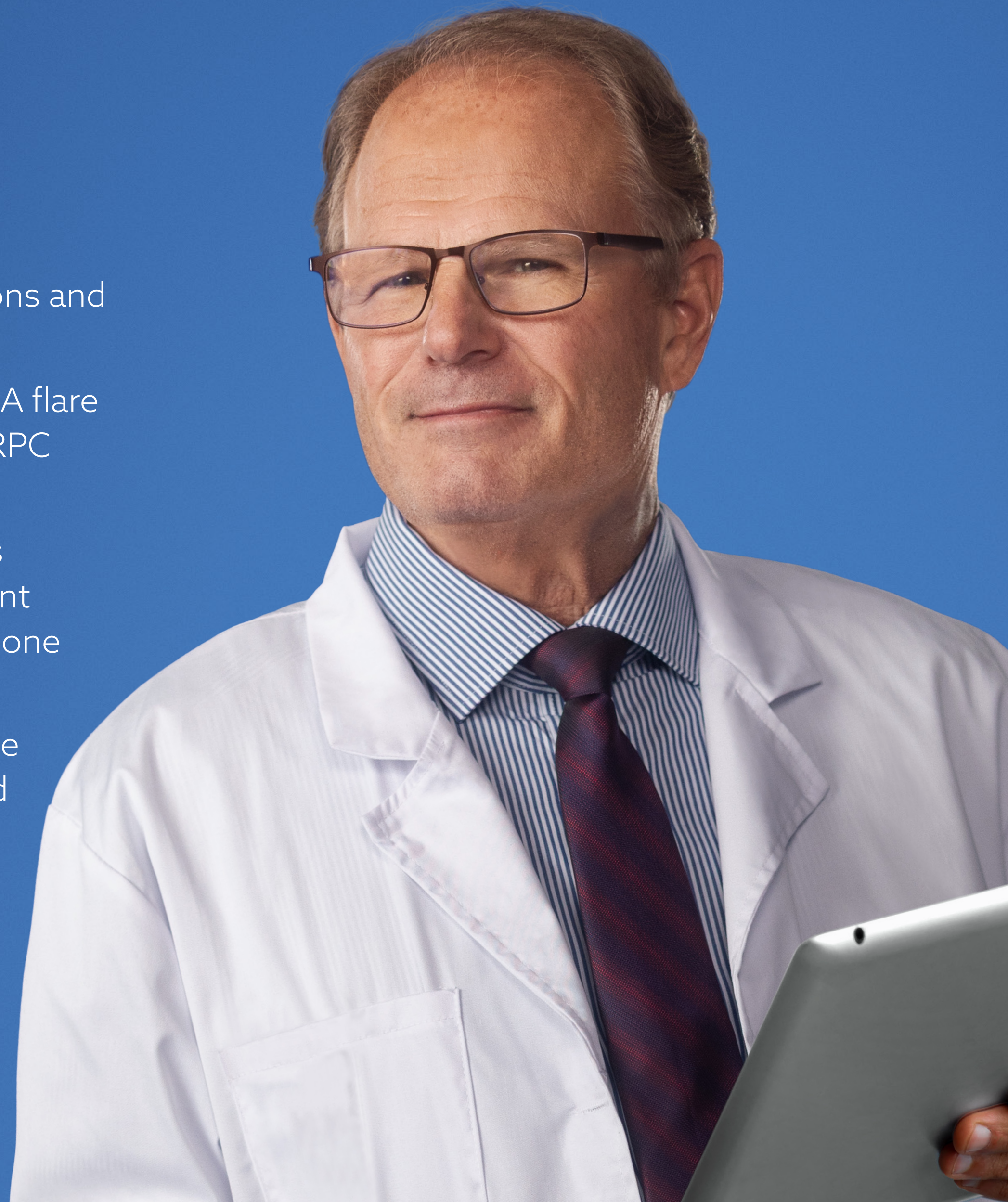
Routine CT and bone scans are essential for comprehensive assessment.³

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 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 toxicity⁶

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.



Indication

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibition (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.

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

 **PLUVICTO®**
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE



INITIAL PET SCAN
11/2017

PET SCAN AFTER 4 CYCLES
5/2018

Individual patient results will vary.

73-YEAR-OLD PSMA+ mCRPC PATIENT, POST-ARPI, POST-TAXANE⁷

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.

Please see Important Safety Information throughout and on pages 10-11 and full [Prescribing Information](#).

 **PLUVICTO[®]**
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

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+ mCRPC patient*



Not an actual patient or care partner.

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.

To minimize radiation exposure to others, advise patients to limit close contact (less than 3 feet) with household contacts 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 bedroom from household contacts 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 the PSMAfore study, grade 3 or 4 decreased hemoglobin (7%), decreased leukocytes (4.4%), decreased neutrophils (3.5%), and decreased platelets (2.7%) occurred in patients treated with PLUVICTO.

One death occurred due to bone marrow failure during long-term follow-up in a patient who received PLUVICTO. In the VISION study, 4 myelosuppression-related deaths occurred.

Please see Important Safety Information throughout and on pages 10-11 and full [Prescribing Information](#).

 **PLUVICTO®**
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE



Discuss how a **targeted option** could evolve the story.

VISION was a pivotal trial in PSMA+ 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 ($\geq 20\%$) in patients who received PLUVICTO + BSOC were fatigue, dry mouth, nausea, back pain, arthralgia, decreased appetite, and constipation⁶

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)

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 the PSMAfore study, grade 3 or 4 acute kidney injury (1.3%) occurred in patients treated with PLUVICTO.

Please see Important Safety Information throughout and on pages 10-11 and full [Prescribing Information](#).



More time without progression for the **days that matter most.**

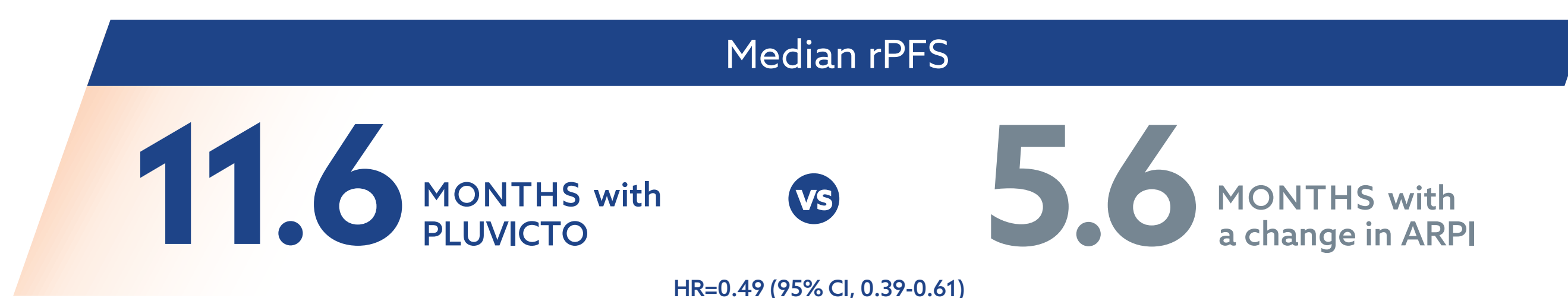
PSMAfore was a trial in PSMA+ mCRPC post-ARPI **without prior mCRPC chemotherapy**⁶

rPFS: Primary end point

In the primary analysis, PLUVICTO achieved statistically significant rPFS⁶

- 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 error⁴

In the updated exploratory analysis, PLUVICTO **more than doubled median rPFS** vs a change in ARPI⁴



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 progression¹¹
- 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 ARPI⁶

*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.

Please see Important Safety Information throughout and on pages 10-11 and full [Prescribing Information](#).



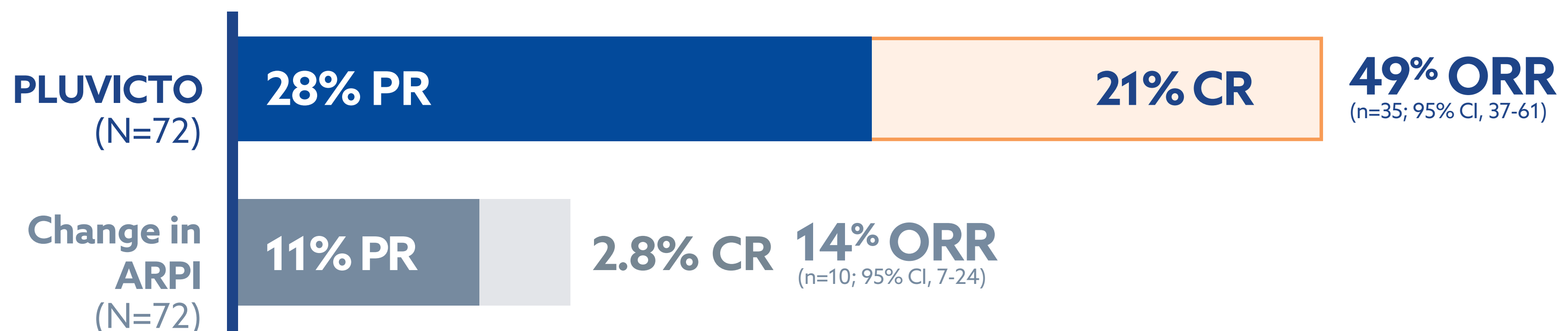
In PSMAfore,

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^a MEASURED BY RECIST 1.1^b



ORR=CR+PR.

^aResponses are based on soft tissue and bone lesion assessment.

^bPatients 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-naïve patients with PSMA+ 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 PSMAfore and VISION studies (N=756), the most common (≥20%) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (83%), decreased hemoglobin (65%), fatigue (49%), dry mouth (46%), decreased platelets (40%), decreased estimated glomerular filtration rate (37%), nausea (35%), decreased neutrophils (31%), decreased calcium (29%), decreased sodium (27%), increased aspartate aminotransferase (26%), increased alkaline phosphatase (24%), arthralgia (22%), decreased appetite (21%), increased potassium (21%), constipation (21%), and back pain (21%).

Please see Important Safety Information throughout and on pages 10-11 and full [Prescribing Information](#).



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 doses¹²

PLUVICTO has a favorable safety profile

Grade ≥ 3 AE rates were lower in the PLUVICTO group with a longer median duration of exposure⁴

- 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 ARPI⁴

PSMAfore: ADVERSE REACTIONS OCCURRING AT $\geq 10\%$ INCIDENCE IN PATIENTS WHO RECEIVED PLUVICTO^{6,a}

| Adverse reactions | PLUVICTO (n=227) | | Change in ARPI (n=232) | |
|--|------------------|-------------------|------------------------|-------------------|
| | 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 |

^aNational Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 5.0.¹³

^bIncludes multiple similar terms.⁶

- Clinically relevant ARs in $<10\%$ of patients who received PLUVICTO included dysgeusia, abdominal pain, peripheral edema, headache, acute kidney injury, weight decreased, urinary tract infection, dry eye, dizziness, dry skin, oral fungal infection, gastroesophageal reflux disease, pyrexia, vertigo, stomatitis, dysphagia, esophagitis, pancytopenia, and bone marrow failure⁶

Not an actual patient or care partner.

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

 **PLUVICTO[®]**
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

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

Laboratory abnormalities

SELECT LABORATORY ABNORMALITIES ($\geq 10\%$) THAT WORSENE FROM BASELINE IN PATIENTS WHO RECEIVED PLUVICTO (BETWEEN-ARM DIFFERENCE OF $\geq 5\%$ ALL GRADES) IN PSMAfore⁶

| Laboratory abnormalities | PLUVICTO ^a | | ARPI ^b | |
|--------------------------------|-----------------------|-------------------|-------------------|-------------------|
| | 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 | | | | |
| Increased alkaline phosphatase | 31 | 8 | 50 | 10 ^c |
| Decreased eGFR | 23 | 0.9 ^c | 22 | 3.5 |
| 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.

^aThe 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

^bThe 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

^cNo grade 4 laboratory abnormalities worsening from baseline were reported.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 $\geq 1\%$ 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 ($\geq 0.5\%$) 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 ($\geq 1\%$) ARs leading to a dose interruption of PLUVICTO in patients who received PLUVICTO were COVID-19 (3.1%) and anemia (1.8%)⁶

Please see Important Safety Information throughout and on pages 10-11 and full [Prescribing Information](#).

Indication and Important Safety Information

Indication

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibition (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 household contacts 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 bedroom from household contacts 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 the PSMAfore study, grade 3 or 4 decreased hemoglobin (7%), decreased leukocytes (4.4%), decreased neutrophils (3.5%), and decreased platelets (2.7%) occurred in patients treated with PLUVICTO. One

death occurred due to bone marrow failure during long-term follow-up in a patient who received PLUVICTO. In the VISION study, 4 myelosuppression-related deaths occurred.

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 the PSMAfore study, grade 3 or 4 acute kidney injury (1.3%) 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.

Important Safety Information

(continued)

Adverse Reactions and Laboratory Abnormalities

In the pooled safety population for the PSMAfore and VISION studies (N=756), the most common ($\geq 20\%$) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (83%), decreased hemoglobin (65%), fatigue (49%), dry mouth (46%), decreased platelets (40%), decreased estimated glomerular filtration rate (37%),

nausea (35%), decreased neutrophils (31%), decreased calcium (29%), decreased sodium (27%), increased aspartate aminotransferase (26%), increased alkaline phosphatase (24%), arthralgia (22%), decreased appetite (21%), increased potassium (21%), constipation (21%), and back pain (21%).

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-naïve 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-naïve 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-naïve 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-naïve 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

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 ARPI⁴

- 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 ARPI⁶

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 exposure⁴
- 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.

Indication

PLUVICTO[®] (lutetium Lu 177 vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibition (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.

Please see Important Safety Information throughout and on pages 10-11 and full [Prescribing Information](#).