FDA APPROVED FOR PATIENTS WITHOUT PRIOR CHEMOTHERAPY*

The Bullseye

PLUVICTO IN PRACTICE

ISSUE #3

In this issue, 2 experts provide their experiences and perspectives on starting PLUVICTO in a large, integrated urology practice and using it for metastatic castration-resistant prostate cancer (mCRPC) without prior chemotherapy.

THIS ISSUE'S EXPERTS

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The perspectives provided within this newsletter by Dr Pieczonka and Dr Finkelstein are their own and not reflective of their affiliations. The medical experts in this newsletter have been paid by Novartis to provide their perspectives. This newsletter is not intended to be and does not serve as medical advice, guidance, or recommendations from Novartis.

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

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 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.

Please see additional Important Safety Information throughout and on page 7, and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

In PSMA+ mCRPC

PLUVICTO is the first and only PSMA-targeted radioligand therapy to significantly delay progression after only 1 ARPI

> We now have **an opportunity to use lutetium in a much broader patient population** with prostate cancer. Taking these patients from an ability to get this medicine is very important to me.
>
> **Dr Pieczonka**

Dr Pieczonka has been compensated for his time by Novartis Pharmaceuticals Corporation.

PLUVICTO, lutetium Lu 177 vipivotide tetraxetan, is approved for patients without prior chemotherapy.[1,*]

PLUVICTO was evaluated in PSMAfore, a randomized, multicenter, open-label, active-controlled study that compared PLUVICTO vs a change in ARPI[1,2]

- PSMAfore enrolled 468 men with PSMA+ mCRPC who had progressed on 1 prior ARPI

Median rPFS (primary end point) in the PSMAfore trial with PLUVICTO vs a change in ARPI[1]:

- Primary analysis: 9.3 months vs 5.6 months (HR = 0.41 [95% CI: 0.29-0.56]; *P*<.0001)[1]
  - PLUVICTO achieved statistically significant rPFS
- Updated exploratory analysis: **11.6 months vs 5.6 months** (HR = 0.49 [95% CI: 0.39-0.61])[2,†]
  - PLUVICTO more than **doubled median rPFS** vs a change in ARPI

CI, confidence interval; HR, hazard ratio; rPFS, radiographic progression-free survival.
*For patients considered appropriate to delay taxane-based chemotherapy.[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.[2]

> PLUVICTO showed a **delay in radiographic progression-free survival**. This was an appropriate end point to show **there was benefit for patients**.
>
> **Dr Pieczonka**

Dr Pieczonka has been compensated for his time by Novartis Pharmaceuticals Corporation.

Scan this QR code to hear about the use of PLUVICTO for mCRPC before chemotherapy

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 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.

Please see additional Important Safety Information throughout and on page 7, and full Prescribing Information.

Lutetium Lu 177 vipivotide tetraxetan (PLUVICTO) is a National Comprehensive Cancer Network® (NCCN®)-recommended option for patients with mCRPC[3]

> We were very excited to see this on the **NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®)**
>
> **Dr Finkelstein**

Dr Finkelstein has been compensated for his time by Novartis Pharmaceuticals Corporation.

FDA approves PLUVICTO for PSMA+ mCRPC[4]
March 23, 2022

May 10, 2022
The NCCN Guidelines® version 4.2022 included lutetium Lu 177 vipivotide tetraxetan (PLUVICTO)[5]

FDA approves PLUVICTO for earlier use, before chemotherapy, in PSMA+ mCRPC[6]
March 28, 2025

April 16, 2025
The NCCN Guidelines version 2.2025 included the expanded indication of lutetium Lu 177 vipivotide tetraxetan (PLUVICTO)[7]

> When lutetium Lu 177 vipivotide tetraxetan (PLUVICTO) was approved, the **NCCN embraced that within the guidelines.** I think that speaks to the power of the data.
>
> **Dr Pieczonka**

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Inclusion of lutetium Lu 177 vipivotide tetraxetan (PLUVICTO) in the NCCN Guidelines affirms its evidence-based clinical value, supports its designation as medically necessary, and strengthens its position for favorable payer coverage and reimbursement.

FDA, US Food and Drug Administration; PSMA+, PSMA-positive.

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Scan this QR code or visit www.pluvicto-hcp.com to learn more about PLUVICTO from leading medical experts in prostate cancer

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout and on page 7, and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

Novartis is committed to delivering an exceptional PLUVICTO experience

> We said we want to give this agent and **within 5 days, we had PLUVICTO**.
>
> **Dr Finkelstein**

Dr Finkelstein has been compensated for his time by Novartis Pharmaceuticals Corporation.

- There are **over 700** PLUVICTO treatment sites in the United States[8]
- **~90%** of PLUVICTO-eligible patients are within 30 miles of a treatment site[9,*]
- PLUVICTO can now be administered in all 50 states and Puerto Rico
- PLUVICTO can be delivered within 5 days of order placement,[†] so your patients can be treated as soon as possible[8]
- **~99.9%** on-time delivery for all PLUVICTO orders[8]
- **~83K** doses shipped from launch to date[8,‡]
- **~23K** patients treated from launch to date[8,§]

PLUVICTO is also available as a prefilled syringe

Prefilled syringe

Not actual size.

HCP, health care professional.
*Based on claims data and latest HCP location of patients.[9]
[†]Exceptions may apply for syringe form and select geographic locations.[8]
[‡]US commercial orders only.[8]
[§]Based on data from August 2025.[8]

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout and on page 7, and full Prescribing Information.

Novartis Patient Support™, a comprehensive program to help patients start, stay, and save on PLUVICTO

> It's very important that we have our industry partners help us... **Novartis has a variety of support mechanisms.**
>
> **Dr Pieczonka**

Dr Pieczonka has been compensated for his time by Novartis Pharmaceuticals Corporation.

Novartis can support you throughout your patient's journey with:

Insurance and reimbursement

- Support includes benefits verification, prior authorization requirements, appeals support, billing, coding, and reimbursement education

Financial support

- Eligible patients may pay as little as $0* per dose
- Enrollment is required to determine eligibility and participation

Acquisition

- Support includes new treating site onboarding, access to ordering platform, and real-time delivery tracking

Patient education

- Live 1-on-1 support is available for patients starting treatment
- Our Patient Navigators can help answer the most common treatment questions

LEARN MORE ABOUT NOVARTIS PATIENT SUPPORT.

Benefit investigation can be completed in less than **2 business days.**†

Scan the QR code and fax the Start Form to **1-884-638-7329**

Ask your Novartis oncology specialist to connect with your local access & reimbursement representative to help answer detailed questions on payer coverage, patient affordability, purchasing, pricing, and reimbursement.

*Limitations apply. Valid only for those patients with commercial insurance. Not valid under Medicare or any other federal or state program. Offer subject to a maximum benefit per course of treatment. See complete Terms and Conditions in the Start Form for details.
†Primary plans only; an additional 1 to 2 days if secondary plan coverage review is required.

IMPORTANT SAFETY INFORMATION (continued)

Renal Toxicity (continued)
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 page 7, and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

Scan this QR code or visit www.pluvicto-hcp.com to learn more about the clinical data for PLUVICTO.

Multidisciplinary collaboration is crucial to providing patients with PLUVICTO[10]

> Having **different doctors** with different focus and different skill sets about how to achieve their best outcome is probably the **best way to have patients achieve the best overall result** in this difficult disease process.
>
> **Dr Finkelstein**

Dr Finkelstein has been compensated for his time by Novartis Pharmaceuticals Corporation.

- A multidisciplinary approach to prostate cancer care can begin as early as diagnosis and treatment selection[10]
- Communications between HCPs can involve[10]:
  - Consulting and assessing treatments for patients, particularly in unclear or borderline cases
  - Managing disease and treatment-related adverse events (AEs)
  - Optimizing treatment regimens
  - Counseling provided across the disciplines
- Close coordination between HCPs can help facilitate a **smooth continuum of care** for patients as they start and continue on PLUVICTO[11,12]

Scan this QR code to hear how 2 experts provided PLUVICTO in a urology setting

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.

Please see additional Important Safety Information throughout and on page 7, and full Prescribing Information.

PLUVICTO Indication and Full Important Safety Information

Indication

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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 full Prescribing Information at www.pluvicto.com.

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PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

FDA APPROVED FOR PATIENTS WITHOUT PRIOR CHEMOTHERAPY

Accelerating the PLUVICTO referral process to help your patients get started on PLUVICTO

> As a practice, you're going to need to be able to offer and deliver lutetium to the appropriate patients.
>
> **Dr Finkelstein**

Dr Finkelstein has been compensated for his time by Novartis Pharmaceuticals Corporation.

Get your patients on PLUVICTO promptly after only 1 ARPI[1]

3 WAYS TO ACCELERATE THE PLUVICTO REFERRAL PROCESS

Order PSMA-PET scan at first sign of progression

1 **Confirm PSMA+ status for your patients with mCRPC**

TIP: 2 increases in PSA measured at least 1 week apart are considered a sign of progression for inclusion criterion in the PSMAfore clinical trial[2]

Proactively identify PLUVICTO Treatment Centers

2 **Use the PLUVICTO Treatment Center Locator* to find sites in your local area**

SUPPORT: Novartis Patient Support and your Oncology Specialist can help you find treatment centers closest to you and your patients

Start the referral process

3 **Connect with your selected treatment center to understand the referral requirements**

SUPPORT: Novartis Patient Support can help you understand patient coverage and affordability. Benefit investigation can be completed in less than 2 business days†

PET, positron emission tomography; PSA, prostate-specific antigen.
*There are over **700** PLUVICTO treatment sites in the United States. Please note that the PLUVICTO Treatment Centers listed are only those that have authorized their participation on the PLUVICTO website.[9]
†Primary plans only; an additional 1 to 2 days if secondary plan coverage review is required.

IMPORTANT SAFETY INFORMATION (continued)

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

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- have received prior taxane-based chemotherapy

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