PYLARIFY TruVu™
Piflufolastat F 18 Injection

An updated formulation of the #1 utilized PSMA PET agent in the US[1]

Actor portrayals.

The effectiveness of PYLARIFY TruVu was established based on two robust clinical studies with an older formulation of piflufolastat F 18.[2]

OSPREY was a phase 2/3 clinical trial of 385 patients. Cohort A studied patients with high-risk prostate cancer (n=268). The co-primary endpoints were specificity (95%-98%) and sensitivity (28%-39%). Secondary endpoints included positive predictive value (PPV = 72%-81%).[2,3]

CONDOR was a phase 3 trial of 208 patients with suspected recurrent or metastatic prostate cancer. The primary endpoint was correct localization rate (CLR = 85%-87%).[2,4]

The addition of a radiolytic stabilizer has the potential to increase availability and reliability.[2]

F 18=radioisotope fluorine-18; PET=positron emission tomography; PSMA=prostate-specific membrane antigen.

INDICATION

PYLARIFY TRUVU (piflufolastat F 18) Injection is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy.
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Risk of Image Misinterpretation

Imaging interpretation errors can occur with PYLARIFY TRUVU imaging. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of PYLARIFY TRUVU for imaging biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY TRUVU for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by risk factors such as Gleason score and tumor stage. PYLARIFY TRUVU uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes and in normal tissues. Clinical correlation, which may include histopathological evaluation, is recommended.

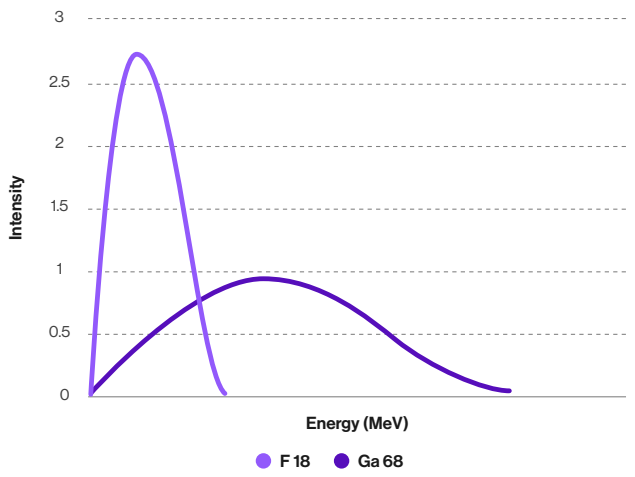
Please see additional Important Safety Information on page 14 and the full Prescribing Information for PYLARIFY TruVu.

THE ADVANTAGES OF AN F 18 ISOTOPE

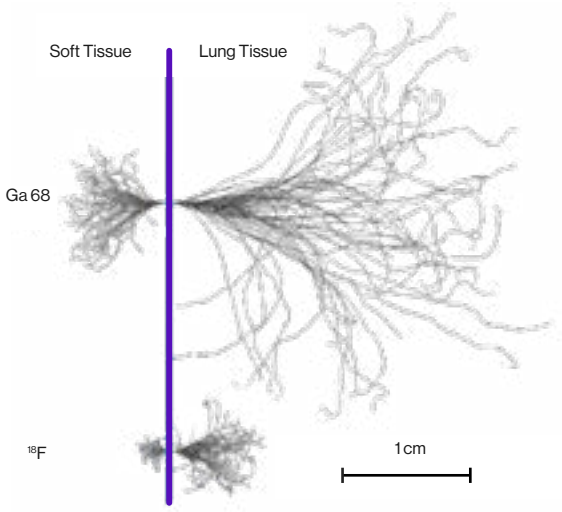
Better spatial resolution and less noise in comparison to Ga 68[5,6]

As demonstrated through experimental phantom measurements and Monte Carlo simulations.

Positron energy spectrum for the decay of G 68 and F 18



Monte Carlo Simulation of Different Positron Tracks from the Decay of Ga 68 and F 18 in Human Lung and Soft Tissues



F 18 provides better resolution in PSMA PET scans
due to the lower endpoint positron energy emission, which results in a shorter distance traveled by positrons prior to annihilation[5,6]

Ga 68=radioisotope gallium-68.

THE ADVANTAGES OF AN F 18 ISOTOPE (CONTINUED)

More lesions detected by an F 18 imaging agent vs a Ga 68 imaging agent[7]

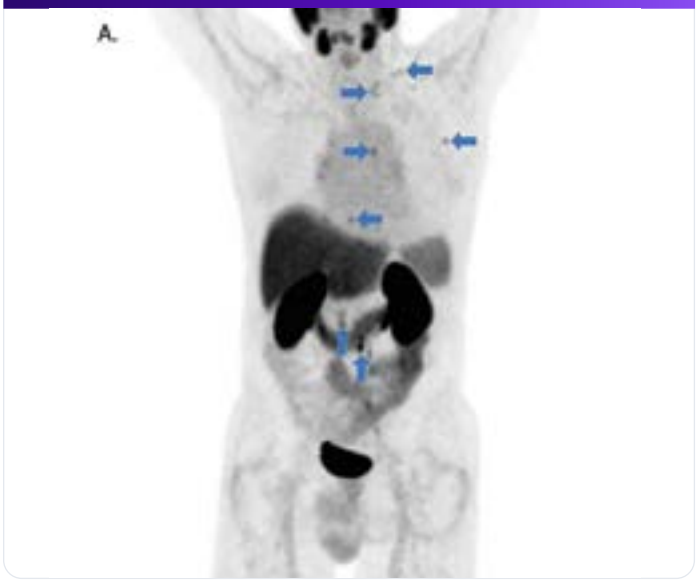
Fourteen BCR patients underwent PET/CT with F 18 and Ga 68 PSMA-targeted tracers[7]

In a comparison between results obtained using both tracers, **an F 18 agent detected additional lesions in 21% of patients (3 of 14)**, based on the number of PSMA-positive lesions, SUV_{max} values, and lesion-to-background ratios.[7]

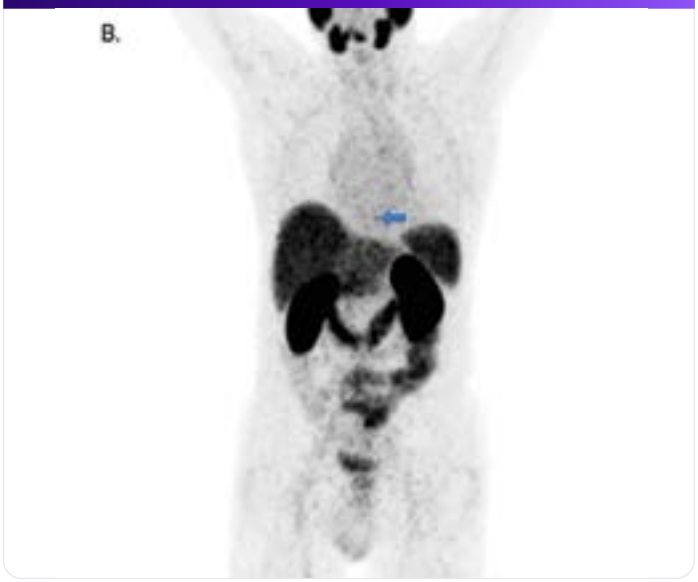
Limitations of note[7]:

- Tracers were not examined under identical conditions
- Additional lesions detected may include false-positive findings
- The data are not powered to be statistically significant and are descriptive in nature

MIP with F 18



MIP with Ga 68



Adapted with permission from Dietlein M, Kobe C, Kuhnert G, et al. Comparison of [^{18}F]DCFPyL and [^{68}Ga]Ga-PSMA-HBED-CC for PSMA-PET imaging in patients with relapsed prostate cancer. *Mol Imaging Biol*. 2015;17(4):575-584.

F 18 can offer advantages for PSMA PET scans
for PCa detection and evaluation[5-7]

BCR=biochemical recurrence; CT=computed tomography; MIP=maximum intensity projection; PCa=prostate cancer; SUV_{max}=maximum standardized uptake value.

PYLARIFY TruVu CAN

PYLARIFY TruVu™ (piflufolastat F 18) is an updated formulation of piflufolastat F 18 that combines the same diagnostic properties of its predecessor with a radiolytic stabilizer to increase batch production so we can scale to support your future needs[2]

With PYLARIFY TruVu you can expect:

SAME DIAGNOSTIC PERFORMANCE[2]

POTENTIAL FOR INCREASED AVAILABILITY AND RELIABILITY WITH ADDITIONAL DOSES PER BATCH[2]

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Hypersensitivity Reactions

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PYLARIFY TruVu™
Piflufolastat F 18 Injection

WE CAN DELIVER DIAGNOSTIC PRECISION[2-4]

PYLARIFY TruVu: Effectiveness and safety have been established based on data from OSPREY—a clinical study of another formulation of piflufolastat F 18[2,3]

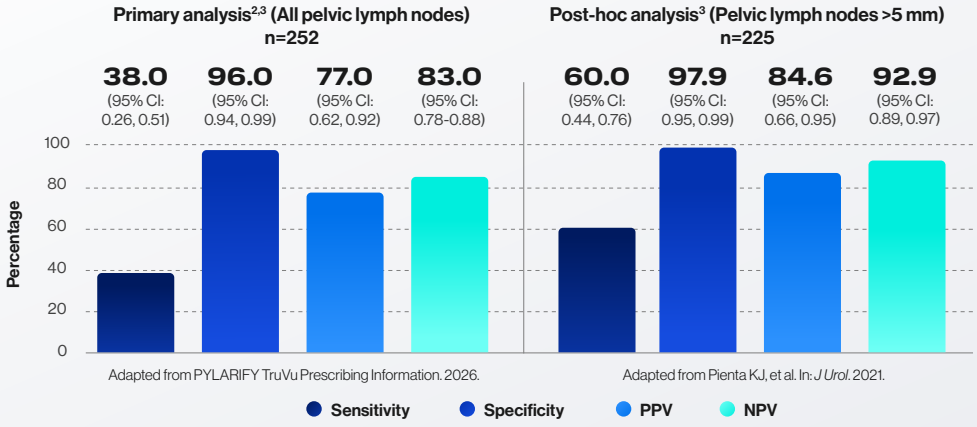
OSPREY was a robust, prospective, multicenter, phase 2/3 clinical trial of 385 patients with either high-risk prostate cancer (Cohort A; n=268) or radiologic evidence of recurrence (Cohort B; n=117). In Cohort A, the co-primary endpoints were specificity and sensitivity; the secondary endpoints were PPV, NPV, detection of M1 disease, and detection of primary tumor within the prostate. In Cohort B, sensitivity and PPV were secondary endpoints.[2,3]

Cohort A: Increased Clarity With Tumors[2,3]

In the primary analysis, the specificity co-primary endpoint with PSMA-targeted PET scan with piflufolastat F 18 was met (the lower limits of the 95% CIs for all readers were >80%), but the sensitivity co-primary endpoint was not met.[3]

Post-hoc analysis was conducted evaluating PET/CT for detection of nodal metastases >5 mm. Twenty-seven patients were excluded whose largest nodal metastasis was ≤5 mm.[3]

Pre-Specified and Post-Hoc Analysis: Sensitivity, Specificity, PPV, NPV*



*Median values were determined by three independent physicians and histopathology truth standard was pathology specimens (nodal packets collected at PLND) evaluated by pathologists blinded to imaging results.[2,3]

Compared to standard imaging, PSMA-targeted PET scan with piflufolastat F 18 delivered[3]:

- **Higher specificity** (96.3%-98.9% vs 65.1%)
- **Nearly 3 times the PPV** (78.1%-90.5% vs 28.3%)
- **Similar sensitivity to standard imaging** (30.6%-41.9% vs 42.6%)

CI=confidence interval; NPV=negative predictive value; PLND=pelvic lymph node dissection; PPV=positive predictive value.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Radiation Risks

PYLARIFY TRUVU exposes patients to radiation. Radiation exposure is associated with a dose-dependent increased risk of cancer. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

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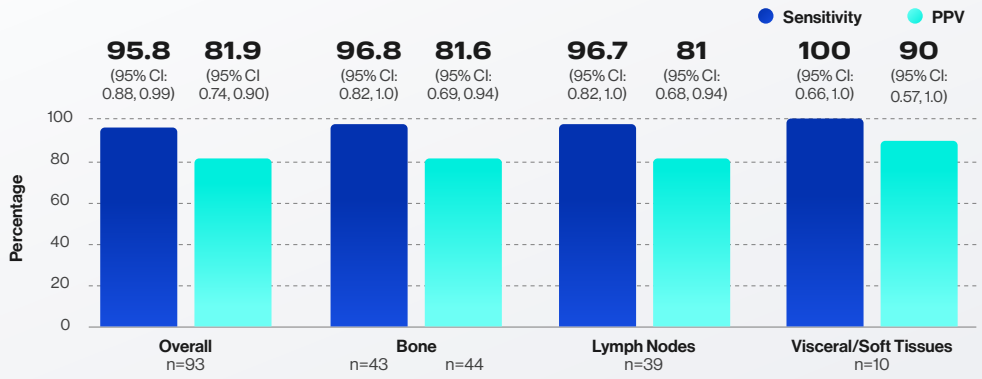
WE CAN DELIVER DIAGNOSTIC PRECISION[2-4] (CONTINUED)

Cohort B: Efficacy Outcomes in Patients With Radiologic Recurrence or Metastasis

Region-level PPV: 81%-90% in men with radiographic recurrence across all sites of disease of metastasis, including bone[3]*

In Cohort B (93 evaluable patients, median prostate-specific antigen (PSA) 11.3 ng/mL), median sensitivity and positive predictive value for extraprostatic lesions were 95.8% (87.8%-99.0%) and 81.9% (73.7%-90.2%), respectively.

Diagnostic Performance: Sensitivity and PPV Across Disease Sites Including Bone[3*†]



*Median values were determined by three independent physicians and histopathology truth standard was pathology specimens (biopsied tissue of at least 1 lesion identified on conventional imaging) evaluated by pathologists blinded to imaging results.[2,3]

†Formal hypothesis testing was not employed for Cohort B. Results are descriptive, no definitive conclusions can be made.[3]

High sensitivity across regions ensures a low false-negative rate[3]

In OSPREY Cohort A, piflufolastat F 18 delivered substantial to almost perfect reader agreement[3,8,9‡]:

Substantial inter-reader agreement in Cohort A
(0.78 Fleiss kappa)

Moderate to almost perfect intra-reader agreement in Cohort A and B
(0.79–1.0 Cohen's kappa)

‡Substantial agreement=Fleiss kappa of 0.61-0.80; Moderate to almost perfect intra-reader agreement=Cohen's kappa of 0.79-1.0.

CLR=correct localization rate; PSA=prostate-specific antigen.

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

The most frequently reported adverse reactions were headaches, dysgeusia and fatigue, occurring at rate of ≤2% during clinical studies. In addition, a delayed hypersensitivity reaction was reported in one patient (0.2%) with a history of allergic reactions.

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PYLARIFY TruVu™
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IN PATIENTS WITH SUSPECTED RECURRENCE BASED ON ELEVATED PSA LEVELS

WE CAN DELIVER DIAGNOSTIC PRECISION[2-4]

PYLARIFY TruVu: Effectiveness and safety have been established based on data from OSPREY—a clinical study of another formulation of piflufolastat F 18[2]

CONDOR was a robust, multicenter, phase 3 trial of 208 patients with suspected recurrent or metastatic prostate cancer with negative or equivocal results using standard imaging. The primary endpoint was CLR*; the key secondary endpoint was the percentage of patients with a change in intended treatment plan[2,4]

CONDOR: Efficacy Outcomes in Patients With Recurrent PCa Based on Rising PSA

CLR Validates Precision

CLR measures how often a positive scan accurately maps lesions to their anatomical locations[2,4]

(CLR = PPV + anatomical precision)

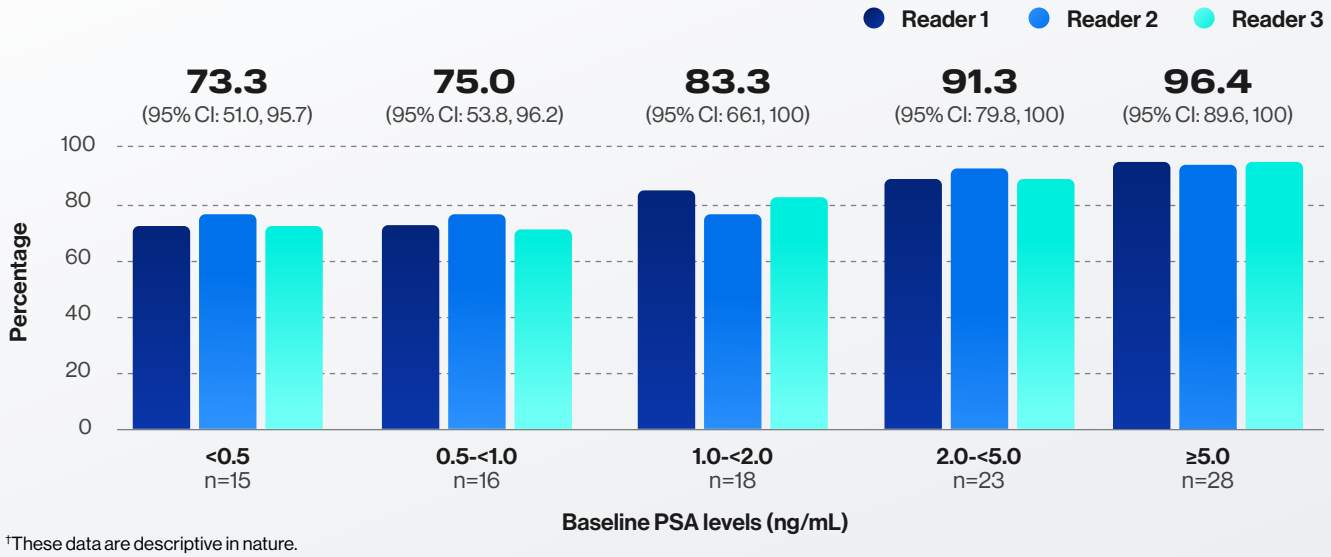
High CLR: Surpassed Primary Endpoint Threshold in All Readers[2,4]*

85%-87%
IN BCR

These results significantly exceeded the predetermined threshold of 20% for all 3 readers

*CLR was assessed against a composite standard of truth that included histopathology, correlative imaging and/or PSA response following directed therapy, as applicable.[4]

CLR at All Evaluated PSA Levels[4†]



†These data are descriptive in nature.

Even in patients with low PSA levels, CLR can demonstrate accurate disease detection[4]

IMPORTANT SAFETY INFORMATION (continued)

DRUG INTERACTIONS

Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, may result in changes in uptake of PYLARIFY TRUVU in prostate cancer. The effect of these therapies on performance of PYLARIFY TRUVU PET has not been established.

To report suspected adverse reactions for PYLARIFY TRUVU, call 1-800-362-2668 or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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PYLARIFY TruVu™
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IN PATIENTS WITH SUSPECTED RECURRENCE BASED ON ELEVATED PSA LEVELS

WE CAN DELIVER DIAGNOSTIC PRECISION[2-4] (CONTINUED)

High True Positives, Low False Positives[4]

High true positives with low false positives provide additional confirmation of accuracy in BCR, enabling physicians to make treatment choices with confidence. In contrast, high false positives may throw off accurate assessment of the presence and extent of prostate cancer, risking overtreatment.

86%
TRUE POSITIVES*

14%
FALSE POSITIVES*

*Median result of 3 independent readers.

In CONDOR, piflufolastat F 18 delivered substantial to almost perfect reader agreement[4†]:

Substantial
inter-reader agreement
(0.65 Fleiss kappa)

Strong to almost perfect
intra-reader agreement
(0.81–1.0 Cohen's kappa)

†Substantial agreement=Fleiss kappa of 0.61-0.80; strong to almost perfect intra-reader agreement=Cohen's kappa of 0.80-1.0.[8,9]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Risk of Image Misinterpretation

Imaging interpretation errors can occur with PYLARIFY TRUVU imaging. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of PYLARIFY TRUVU for imaging biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY TRUVU for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by risk factors such as Gleason score and tumor stage. PYLARIFY TRUVU uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes and in normal tissues. Clinical correlation, which may include histopathological evaluation, is recommended.

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PYLARIFY TruVu™
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WE CAN DELIVER ON SAFETY[2]

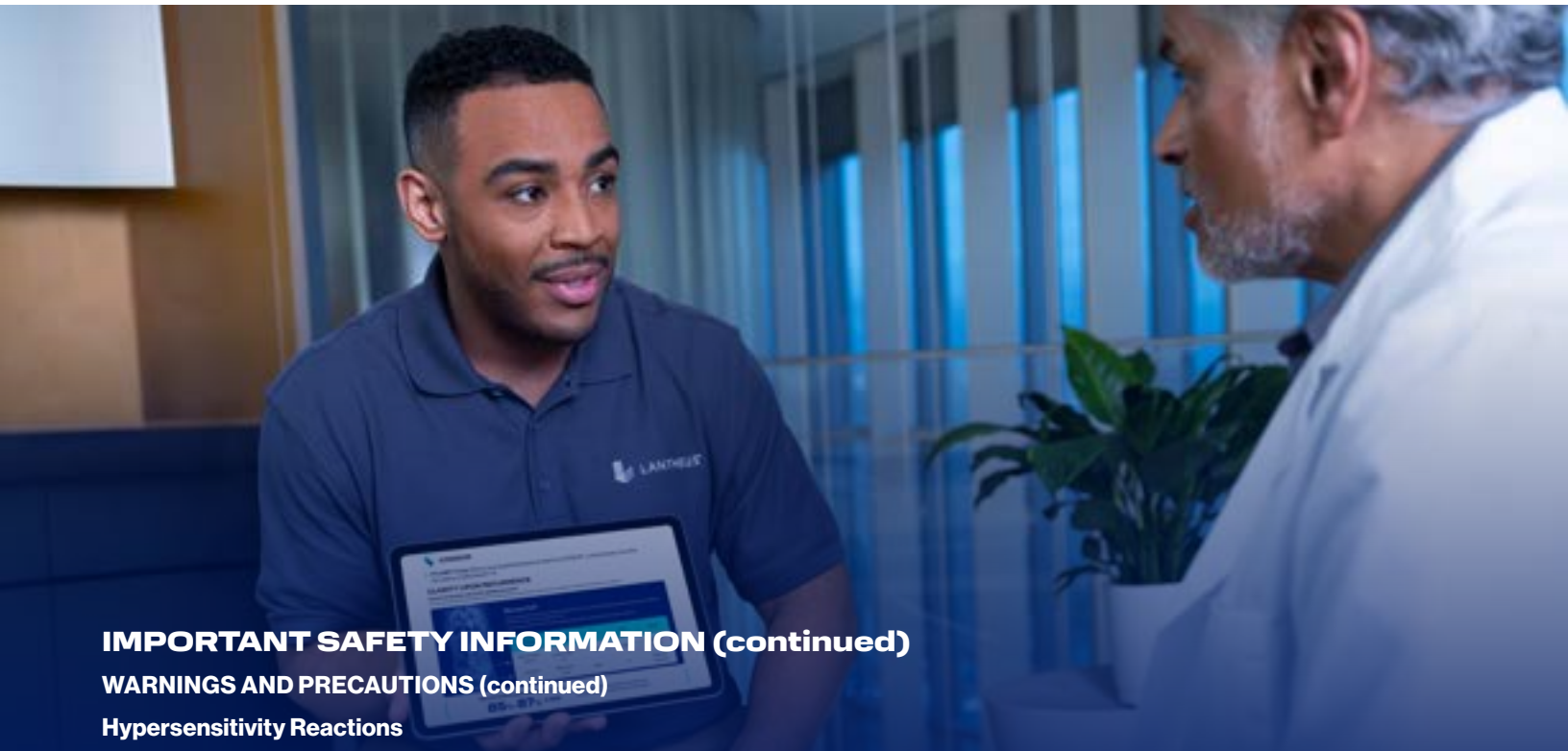
PYLARIFY TruVu: Effectiveness and safety have been established based on data from OSPREY and CONDOR—two clinical studies of another formulation of piflufolastat F 18[2]

Adverse reactions that occurred in >0.5% of patients in OSPREY and CONDOR (N=593)[2]*

Adverse reaction	n (%)
Headache	13 (2.0%)
Dysgeusia	10 (2.0%)
Fatigue	7 (1.0%)

*In addition, a hypersensitivity reaction was reported in 1 patient (0.2%) with a history of allergic reactions.[2]

Monitor patients for hypersensitivity reactions, particularly patients with a history of allergy to other drugs and foods. Reactions may not be immediate. Always have trained staff and resuscitation equipment available.[2]



IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Hypersensitivity Reactions

Monitor patients for hypersensitivity reactions, particularly those with a history of allergy to other drugs and foods. Reactions may be delayed. Always have trained staff and resuscitation equipment available.

Actor portrayals.

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PYLARIFY TruVu™
Piflufolastat F 18 Injection

WE CAN DELIVER ON SUPPLY[2]

PYLARIFY TruVu is widely available through an extensive multi-partner F 18 distributor supply network ensuring convenient and reliable supply when and where you need it.[1] Lantheus is committed to continued expansion of our manufacturing network and excellent customer service.

Reliable supply for your practice

With cyclotron-based production, PYLARIFY TruVu can scale to meet your growing needs[2,10]

Coverage and reliability

Available for over 60 manufacturing facilities in the US and Puerto Rico—and actively expanding[1]

Multiple daily runs

And delivery on weekends, dependent on location

If a manufacturing site experiences batch issues, our dedicated Lantheus Customer Experience team can help. This team can:

- Explore all options to meet demand
- Monitor and address customer escalations
- Communicate manufacturing site calibration times

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Radiation Risks

PYLARIFY TRUVU exposes patients to radiation. Radiation exposure is associated with a dose-dependent increased risk of cancer. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

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PYLARIFY TruVu™
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YOU CAN HAVE CLARITY MAKING THE CALL[3,4,11,12]

PYLARIFY TruVu: Effectiveness and safety have been established based on data from OSPREY and CONDOR—two clinical studies of another formulation of piflufolastat F 18[2]

Patient Impact from Disease Staging

In OSPREY Cohort A,

26.9%

(72/268) of patients at initial staging who were thought to have localized disease based on standard imaging were upstaged to N1 or M1 after physicians reviewed their scans[11]*

*Scans were assessed by 3 blinded, independent central readers.[11]

See OSPREY Cohort A Study Data on page 5.

In OSPREY Cohort B,

57.6%

(19/33) of patients with no evidence of distant metastases on standard imaging were found to have PSMA-positive lesions and were upstaged[3]†

†11 of 19 patients underwent targeted biopsy and 10/11 (91%) were confirmed to have prostate cancer on pathology.[12]

See OSPREY Cohort B Study Data on page 6.

Study Limitation: OSPREY Cohort A was a single-arm study in high-risk, treatment-naïve prostate cancer patients undergoing prostatectomy. Results may not be generalized to broader populations. Diagnostic performance was assessed using lesion-level histopathology and was not designed to evaluate clinical outcomes or infer causality.[12]

Patient Impact from Treatment Planning

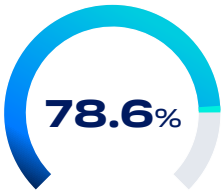
In CONDOR,

63.9%

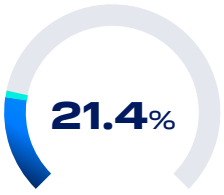
(131/205) of patients with BCR who had negative/noninformative standard imaging had a change in intended treatment after physicians reviewed their scans[4]‡

‡Physicians completed pre- and post-medical management questionnaires for 205 patients.

See full CONDOR Study Design on page 7.



(103/131) of the changes were based on positive findings[4]



(28/131) of the changes were based on negative findings[4]

Study Limitation: CONDOR was a prospective, single-arm study assessing intended management changes based on physician assessment without randomized comparators or evaluation at downstream clinical outcomes. Results were descriptive and based in a selected BCR population with limited histopathologic confirmation.[4]

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

The most frequently reported adverse reactions were headaches, dysgeusia and fatigue, occurring at rate of ≤2% during clinical studies. In addition, a delayed hypersensitivity reaction was reported in one patient (0.2%) with a history of allergic reactions.

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YOU CAN HAVE CLARITY MAKING THE CALL[3,4,11,12] (CONTINUED)

Following imaging results, the most frequent changes to treatment management plans in CONDOR were (N=205)[4]:

SALVAGE LOCAL THERAPY	SYSTEMIC THERAPY	OBSERVATION	PLANNED TREATMENT
TO	TO	TO	TO
SYSTEMIC THERAPY (n=58; 28.3%)	**SALVAGE LOCAL THERAPY** (n=43; 21.0%)	**INITIATING THERAPY** (n=49; 23.9%)	**OBSERVATION** (n=9; 4.4%)

39% of patients with baseline PSA <0.5 ng/mL had a unidirectional change in planned management[13]

Actor portrayal.

IMPORTANT SAFETY INFORMATION (continued)

DRUG INTERACTIONS

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PYLARIFY TruVu™
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Actor portrayals.

THEY CAN

DECIDE THEIR NEXT MOVE

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PYLARIFY TruVu™
Piflufolastat F 18 Injection

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

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- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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PYLARIFY TruVu™
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Trust PYLARIFY TruVu:
An updated formulation of the #1 utilized PSMA PET agent in the US[1]

PYLARIFY TruVu™
Piflufolastat F 18 Injection

DIAGNOSTIC PERFORMANCE — Clarity and accuracy with consistent reader interpretation across 2 robust clinical studies.[2-4*]

AVAILABILITY — Convenient and reliable supply via our extensive, multi-partner F 18 distributor network, with potential for increased batch size and leading support you can count on.[1]

*The safety and effectiveness of PYLARIFY TruVu were established based on two robust clinical studies with an older formulation of piflufolastat F 18.[2]

For over 70 years, Lantheus has led the way forward[1]

INDICATION

PYLARIFY TRUVU (piflufolastat F 18) Injection is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

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Imaging interpretation errors can occur with PYLARIFY TRUVU imaging. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of PYLARIFY TRUVU for imaging biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY TRUVU for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by risk factors such as Gleason score and tumor stage. PYLARIFY TRUVU uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes and in normal tissues. Clinical correlation, which may include histopathological evaluation, is recommended.

Please see Important Safety Information on page 14 and the full Prescribing Information for PYLARIFY TruVu.

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