Lantheus Welcomes CMS' Proposed CY25 Rule for Improved Payment for Specialized Diagnostic Radiopharmaceuticals to Support Patient Access

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BEDFORD, Mass., July 10, 2024 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("Lantheus") (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, announced that it welcomes the Centers for Medicare & Medicaid Services' (CMS') Proposed Medicare Hospital Outpatient Prospective Payment System (OPPS) Rule for calendar year 2025 for improved payment for specialized diagnostic radiopharmaceuticals to support patient access for Medicare beneficiaries.

Today, CMS shared its proposed refinements to the existing packaging policy to improve the accuracy of the overall payment amounts by paying separately for any diagnostic radiopharmaceutical with a per day cost greater than $630. Under current OPPS rules, the costs associated with diagnostic radiopharmaceuticals are packaged into the payment for the nuclear medicine tests. In the proposed rule, innovative diagnostic radiopharmaceuticals, including PYLARIFY, would continue to be paid separately by CMS for traditional Medicare Fee for Service patients in the hospital outpatient setting following the expiry of traditional pass-through payment status. Proposed rules are published annually and will have a 60-day comment period, which will end on September 9, 2024. The final rule will be issued in early November and take effect January 1, 2025.

"At Lantheus, we advocate for equitable access to advanced diagnostic radiopharmaceuticals to aid providers in diagnosing and staging disease, ultimately leading to better patient outcomes," said Brian Markison, Chief Executive Officer of Lantheus. "We are pleased that the proposed rules recognize the value of diagnostic radiopharmaceuticals, including PYLARIFY, and the need to change the current payment system. We will work with coalition partners and advocates to enact separate payment for 2025, while continuing to implement multi-faceted strategies to maintain patient access."

About PYLARIFY® (piflufolastat F 18) Injection

PYLARIFY® (piflufolastat F 18) injection (also known as ^{18}F-DCFPyL or PyL) is a fluorinated small molecule PSMA-targeted PET imaging agent that enables visualization of lymph nodes, bone and soft tissue metastases to determine the presence or absence of recurrent and/or metastatic prostate cancer. For men with prostate cancer, PYLARIFY PET combines the accuracy of PET imaging, the precision of PSMA targeting and the clarity of an F 18 radioisotope for superior diagnostic performance. The recommended PYLARIFY dose is 333 MBq (9 mCi) with an acceptable range of 296 MBq to 370 MBq (8 mCi to 10 mCi), administered as a bolus intravenous injection.[1-6]

PYLARIFY has made a profound impact on the lives of patients battling prostate cancer. It is the number one ordered PSMA PET imaging agent in the U.S., and is a proven diagnostic backed by real-world experience, including in over 350,000 scans across 48 states.

PYLARIFY® (piflufolastat F 18) Injection

Indication

PYLARIFY® (piflufolastat F 18) Injection is a radioactive diagnostic agent 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

Contraindications

None.

Warnings and Precautions

Risk of Image Misinterpretation

Imaging interpretation errors can occur with PYLARIFY 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 for imaging of patients with biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY 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 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 of the suspected prostate cancer site, is recommended.

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

Radiation Risks
Diagnostic radiopharmaceuticals, including PYLARIFY, expose 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.

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

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 in prostate cancer. The effect of these therapies on performance of PYLARIFY PET has not been established.

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

Please read the accompanying full Prescribing Information also available at PYLARIFY.com.

About Lantheus

Lantheus is the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. Headquartered in Massachusetts with offices in Canada and Sweden, Lantheus has been providing radiopharmaceutical solutions for more than 65 years. For more information, visit www.lantheus.com.

Safe Harbor for Forward-Looking and Cautionary Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks and uncertainties and are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by their use of terms such as “would,” “will,” “continuing” and other similar terms. Such forward-looking statements are based upon current plans, estimates and expectations that are subject to risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include (i) the inclusion of separate diagnostic radiopharmaceutical payment in CMS’s final rule; (ii) the timing of the implementation and duration of such a separate payment as part the implementation of a final rule; (iii) the success of our multi-faceted strategies to maintain patient access; and (vi) the risks and uncertainties discussed in our filings with the Securities and Exchange Commission (including those described in the Risk Factors section in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q).

[1]Tan N, Oyoyo U, Bavadian N, et al. PSMA-targeted radiotracers versus 18F fluciclovine for the detection of prostate cancer biochemical recurrence after definitive therapy: a systematic review and meta-analysis. Radiology. 2020;296:44-55. doi:10.1148/radiol.2020191689.

[2]Mena et al. 18 F-DCFPyL PET/CT Imaging in Patients with Biochemically Recurrent Prostate Cancer After Primary Local Therapy J Nucl Med 2020 Jun;61(6):881-889. doi: 10.2967/jnumed.119.234799. Epub 2019 Nov 1.

[3]Alipour et al. Guiding management of therapy in prostate cancer: time to switch from conventional imaging to PSMA PET? Ther Adv Med Oncol. 2019; 11: 1758835919876828.

[4]Werner et al 18F-Labeled, PSMA-Targeted Radiotracers: Leveraging the Advantages of Radiofluorination for Prostate Cancer Molecular Imaging Theranostics 2020; 10(1):1-16. doi:10.7150/thno.37894.

[5]Petersen LJ, Zacho HD. PSMA PET for primary lymph node staging of intermediate and high-risk prostate cancer: an expedited systematic review. Cancer Imaging. 2020;20(1):1-8. doi:10.1186/s40644-020-0290

[6]PYLARIFY® [package insert]. North Billerica, MA: Progenics Pharmaceuticals, Inc., a Lantheus company.

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