

Company

Lantheus

Drug or Device Name

PYLARIFY® injection and PYLARIFY AI™

Category

Medical Technology

Compound/Technical Name

Piflufolastat F 18 injection

Trade Name

PYLARIFY® injection and PYLARIFY AI™

Date of Approval

05/26/2021

Therapeutic Categories

Radioactive diagnostic agent Artificial intelligence platform

Indications

Indications for PYLARIFY®: PYLARIFY® (piflufolastat F 18) Injection is a radioactive diagnostic agent indicated for PET (positron emission tomography) imaging of PSMA (prostate specific membrane antigen) positive lesions in men with prostate cancer: with suspected metastasis who are candidates for initial definitive therapy and/or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. Indications for PYLARIFY AI™: PYLARIFY AI is an artificial intelligence platform developed to assist in standardized quantification of PSMA PET/CT scans. The device that provides general picture archiving and communications system (PACS) tools as well as a clinical application for oncology including marking of regions of interest and quantitative analysis. It is intended to be used by healthcare professionals and researchers for acceptance, transfer, storage, image display, manipulation, quantification and reporting of digital medical images. The system is intended to be used with images acquired using nuclear medicine imaging using PSMA PET/CT.

Background

In the U.S., prostate cancer (PCa) is the 2nd leading cause of cancer death in men and makes up 26% of new cancer diagnoses. Diagnostic imaging for PCa helps assess disease burden to inform treatment decisions (1,2). An early, accurate assessment of disease is critical because while the five-year relative survival rate for patients diagnosed with localized prostate cancer approaches 100%, if distant metastases are present, the five-year survival rate drops to approximately 30% (3). PYLARIFY® (piflufolastat F 18) and PYLARIFY AI™ were developed with an intent to improve imaging of PCa and therapeutic decision-making and ultimately patient outcomes. PYLARIFY was the first commercially available FDA-approved PSMA PET imaging agent for PCa. PYLARIFY targets PSMA, a protein that is

overexpressed on the surface of more than 90% of primary and metastatic prostate cancer cells. PYLARIFY binds to the target, enabling the reader of the PET scan to detect and locate the disease (4). In clinical trials, the results from a PYLARIFY scan resulted in physicians changing treatment plans for 2 out of 3 men with recurrent cancer. The clinical utility of PYLARIFY is enhanced when used with PYLARIFY AI™, the first and only FDA-cleared software as a medical device offering standardized quantitative reporting of PSMA PET/CT images. PYLARIFY AI enables physicians to rapidly detect and quantify disease burden and provides consistent and quantitative assessments of PSMA PET/CT images (6,7). As the use of PSMA PET imaging becomes more widespread, capturing the data to produce quantifiable and reproducible insights across the treatment spectrum will be essential. In 2021, more than 34,000 men in the U.S. died of prostate cancer. Together, these medical advances in detecting and localizing disease may improve the outcome for men fighting prostate cancer.

Development

Approximately ten years ago, a team of scientists at John Hopkins University (JHU) first discovered 18F-DCFPyL. A subsequent proof-of-concept study indicated that PET imaging using 18F-DCFPyL (now known as piflufolostat F 18 or PYLARIFY®) detected high levels of uptake in sites of primary PCa tumors and metastatic disease. Recognizing its unique ability to pinpoint PCa, Progenics Pharmaceuticals, Inc., a subsidiary of Lantheus, in-licensed 18F-DCFPyL from JHU to develop and commercialize this innovation. Using data from two Progenics-sponsored pivotal studies (OSPREY and CONDOR) that demonstrated PYLARIFY's safety and diagnostic performance across the PCa continuum, PYLARIFY received U.S. Food and Drug Administration (FDA) approval on May 26, 2021. Following FDA approval, the Society of Nuclear Medicine and Molecular Imaging, in collaboration with four other expert national and international organizations, updated the Appropriate Use Criteria for PSMA-targeted imaging technology. Meanwhile, the National Comprehensive Cancer Network® Guidelines were revised to include PSMA PET imaging with PYLARIFY, both in the initial evaluation and in the recurrent disease setting for prostate cancer. Currently, Lantheus' networks enable more than 80% of patients and providers access to this transformative imaging agent. PYLARIFY AI was developed to complement the vital insights provided by PYLARIFY PET/CT and offer a consistent, standardized platform to measure PSMA uptake at the lesion level and reproduce image assessments. Following rigorous testing including more than 3,000 scans, the medical device software was launched in November 2021 as PYLARIFY AI after receiving 510(k) FDA clearance in July and is used for acceptance, transfer, storage, image display, manipulation, quantification and reporting of digital medical images.

Innovation

PYLARIFY and PYLARIFY AI represent a paradigm shift in the imaging and management of PCa. PYLARIFY's novelty stems from its ability to combine the accuracy of PET imaging, the precision of PSMA targeting, and the clarity of an 18F radioisotope. It provides physicians with a tool that may detect prostate cancer earlier and more accurately than traditional imaging, allowing physicians and patients the opportunity to personalize treatment with the goal of optimizing outcomes and protecting quality of life. Moreover, because PYLARIFY AI helps HCPs accurately report on, store, and reproduce PSMA assessments, physicians have a clearer picture and standardized method for managing their patients' health. The promise of PYLARIFY is only beginning to be realized. PSMA diagnostics and theranostics are rapidly being introduced into the treatment paradigm for patients with prostate cancer from initial staging to identifying patients with treatment resistant disease who are likely to benefit from a PSMA-targeted therapeutic. PYLARIFY is currently being studied in multiple late-stage radioligand therapy trials as a way to identify patients with advanced disease that may be eligible for these novel treatments. The data from these trials will also be used to inform PYLARIFY AI,

deepening its insight and utility. Contrary to declining mortality rates for many cancers, and in spite of recent therapeutic advances, PCa deaths are rising, with an increase of 5% from 2019 to 2020 (8,9). Given that high-risk PCa is more likely to be advanced at diagnosis, accurate initial assessment of a patient's disease is critical. PYLARIFY's ability to improve disease assessment in PCa may give patients the best opportunity for long-term survival. PYLARIFY's rapid commercial adoption has been unprecedented, and the opportunities for the agent to be used to Find, Fight and Follow disease to improve patient outcomes is only beginning to be utilized.

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[1] Barbosa FG, et al. RadioGraphics. 2019 ;39(1). Available at : <https://pubs.rsna.org/doi/10.1148/rg.2019180079> [2] GU 2020: Biologic and Clinical Rationale for Treatment of the Primary in Low-Volume Metastatic Disease. Available at: <https://www.urotoday.com/conference-highlights/asco-gu-2020/asco-gu-2020-prostate-cancer/119121-asco-gu-2020-biologic-and-clinical-rationale-for-treatment-of-the-primary-in-low-volume-metastatic-diseases.html>. [3] Available at: <https://seer.cancer.gov/statfacts/html/prost.html> [4] Ceci & Fanti. PSMA-PET/CT imaging in prostate cancer: why and when. Clinical and Translational Imaging Volume 7, pages 377-379 (2019). [5] FDA clearance letter for aPROMISE. Food and Drug Administration. July 27, 2021. [6] Nickols N, Anand A, Johnsson K, et al. aPROMISE: a novel automated-PROMISE platform to standardize evaluation of tumor burden in 18F-DCFPyL (PSMA) images of veterans with prostate cancer [published online ahead of print, 2021 May 28]. J Nucl Med. 2021. doi:10.2967/jnumed.120.26186 [7] Johnsson K, Brynolfsson J, Sahlstedt H, et al. Analytical performance of aPROMISE: automated anatomic contextualization, detection, and quantification of [18F]DCFPyL (PSMA) imaging for standardized reporting [published online ahead of print, 2021 Aug 31]. Eur J Nucl Med Mol Imaging. 2021. doi:10.1007/s00259-021-05497-8 [8] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2019. CA Cancer J Clin. 2019;69:7-34 [9] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2020. CA Cancer J Clin. 2020;70:7-30 PYLARIFY Pienta KJ, Gorin MA, Rowe SP, et al. A Phase 2/3 Prospective Multicenter Study of the Diagnostic Accuracy of Prostate Specific Membrane Antigen PET/CT with 18F-DCFPyL in Prostate Cancer Patients (OSPReY). J Urol. 2021 Jul;206(1):52-61. doi: 10.1097/JU.0000000000001698. Epub 2021 Feb 26. PMID: 33634707; PMCID: PMC8556578. Morris MJ, Rowe SP, Gorin MA, et al. CONDOR Study Group. Diagnostic Performance of 18F-DCFPyL-PET/CT in Men with Biochemically Recurrent Prostate Cancer: Results from the CONDOR Phase III, Multicenter Study. Clin Cancer Res. 2021 Jul 1;27(13):3674-3682. doi: 10.1158/1078-0432.CCR-20-4573. Epub 2021 Feb 23. PMID: 33622706; PMCID: PMC8382991. PYLARIFY AI Nickols N, Anand A, Johnsson K, et al. aPROMISE: a novel automated-PROMISE platform to standardize evaluation of tumor burden in 18F-DCFPyL (PSMA) images of veterans with prostate cancer [published online ahead of print, 2021 May 28]. J Nucl Med. 2021. doi:10.2967/jnumed.120.261863 Johnsson, K., Brynolfsson, J., Sahlstedt, H. et al. Analytical performance of aPROMISE: automated anatomic contextualization, detection, and quantification of [18F]DCFPyL (PSMA) imaging for standardized reporting. Eur J Nucl Med Mol Imaging 49, 1041–1051 (2022). <https://doi.org/10.1007/s00259-021-05497-8>

Attachments

- 1656628615Lantheus_Product_Indications_and_Safety_Information_Prix_Galien_2022-06-30.docx
- 1656621920Lantheus_Product_Photos_Prix_Galien_2022-06-30.docx
- 1656621631Lantheus_Pubmed_References_and_Links_Prix_Galien_2022-06-30.docx
- 1656619267Lantheus_Innovation_Prix_Galien_2022-06-30.docx
- 1656618621Lantheus_History_of_the_Development_of_the_Drug_Device_Prix_Galien_2022-06-30.docx
- 1656618235Lantheus_Background_and_Need_for_Drug_Prix_Galien_2022-06-30.docx

