FDA approves second PSMA-targeted PET imaging drug for men with prostate cancer

FDA has approved Pylarify (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214793s000lbl.pdf) (piflufolastat F 18) – a drug for positron emission tomography (PET) imaging of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer. With the approval of Pylarify, certain men with prostate cancer will have greater access to PSMA-targeted PET imaging that can aid health care providers in assessing prostate cancer.

Pylarify is indicated for patients with suspected prostate cancer metastasis (when cancer cells spread from the place where they first formed to another part of the body) who are potentially curable by surgery or other therapy. Pylarify is also indicated for patients with suspected prostate cancer recurrence based on elevated serum prostate-specific antigen (PSA) levels. Pylarify is a radioactive diagnostic agent that is administered in the form of an intravenous injection.

Prostate cancer is the third most common form of cancer in the United States. The American Cancer Society estimates (https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) in 2021, prostate cancer will be the most commonly diagnosed cancer in American men, with 248,530 new cases predicted. Computed tomography (CT) scans, magnetic resonance imaging (MRI) scans, and certain nuclear medicine scans are conventional methods commonly used to image patients with prostate cancer. However, these imaging techniques have limitations in the detection of prostate cancer lesions.

FDA approved the first PSMA-targeted PET imaging drug, Ga 68 PSMA-11 (/node/395565), on December 1, 2020, for the same prostate cancer imaging indications as Pylarify. Marketed Ga 68 PSMA-11 is currently only available locally at two sites in California. Pylarify is anticipated to be distributed from multiple sites throughout the United States.

Once administered via injection, Pylarify binds to PSMA, which is an important pharmacologic target for prostate cancer imaging because prostate cancer cells usually contain elevated levels of the antigen. As a radioactive drug that emits positrons, Pylarify can be imaged by PET to indicate the presence of PSMA-positive prostate cancer lesions in the tissues of the body.

MIM Software Inc. v. Progenics Pharmaceuticals, Inc.
IPR2025-00725
Progenics EX2021

The safety and efficacy of Pylarify were evaluated in two prospective clinical trials with a total of 593 men with prostate cancer who each received one injection of Pylarify. In the first trial, a cohort of 268 patients with biopsy-proven prostate cancer underwent PET/CT scans performed with Pylarify. These patients were candidates for surgical removal of the prostate gland and pelvic lymph nodes and were considered at higher risk for metastasis. Among the patients who proceeded to surgery, those with positive readings in the pelvic lymph nodes on Pylarify PET had a clinically important rate of metastatic cancer confirmed by surgical pathology. The availability of this information prior to treatment is expected to have important implications for patient care. For example, it may spare certain patients from undergoing unnecessary surgery.

The second trial enrolled 208 patients who had rising serum PSA levels after initial prostate surgery or other definitive therapy, and thus had biochemical evidence of recurrent prostate cancer. Prior to a single Pylarify PET/CT scan, all of these patients had baseline conventional imaging performed that did not show definite spread of prostate cancer. Pylarify PET detected at least one positive lesion in at least one body region (bone, prostate bed, pelvic lymph node, other lymph nodes, or soft tissue) in 60% of these patients. In patients with positive Pylarify PET readings who had correlative tissue pathology from biopsies, results from baseline or follow-up imaging by conventional methods, or serial PSA levels available for comparison, local recurrence or metastasis of prostate cancer was confirmed in an estimated 85% to 87% of cases, depending on the reader. Thus, the second trial demonstrated that Pylarify PET can detect sites of disease in patients with biochemical evidence of recurrent prostate cancer, thereby providing important information that may impact the approach to therapy.

The most common adverse reactions to Pylarify were headache, altered taste, and fatigue. There is a risk of hypersensitivity reactions to Pylarify, particularly in patients with a history of allergy to other drugs and foods. There is a risk for misdiagnosis because Pylarify binding may occur in other types of cancer as well as certain non-malignant conditions which may lead to image interpretation errors. There are radiation risks because Pylarify contributes to a patient's overall long-term cumulative radiation exposure, which is associated with an increased risk for cancer.

Pylarify received priority review (/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review) designation for this approval.

FDA granted approval to Progenics Pharmaceuticals, Inc.

MIM Software Inc. v. Progenics Pharmaceuticals, Inc.
IPR2025-00725
Progenics EX2021