FDA approves drug for PET imaging of prostate cancer

December 3 2020

(HealthDay)—The U.S. Food and Drug Administration approved the

first drug for positron emission tomography (PET) imaging of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer, the agency announced Tuesday.

Approval of the radioactive diagnostic agent Gallium 68 PSMA-11 (Ga 68 PSMA-11) was granted to the University of California Los Angeles (UCLA) and the University of California San Francisco and their nuclear medicine teams. The approval provides physicians with a new imaging approach to detect prostate cancer throughout the body in patients with suspected metastasis or recurrence based on rising prostate-specific antigen (PSA) levels.

The FDA based its approval on safety and efficacy data from two prospective clinical trials. The first trial included 325 patients with biopsy-proven prostate cancer who were candidates for surgical removal of the prostate gland and pelvic lymph nodes and had a high risk for metastasis. The patients underwent PET/computed tomography (CT) or PET/magnetic resonance imaging (MRI) scans with a single intravenous injection of Ga 68 PSMA-11. Surgical pathology confirmed that those with positive readings in the pelvic lymph nodes on Ga 68 PSMA-11 PET had a clinically important rate of metastatic cancer.

The second study, which was published in *JAMA Oncology* last June, involved 635 patients with suspected prostate cancer recurrence based on rising serum PSA levels, all of whom received a single Ga PSMA-11 PET/CT scan or PET/MRI scan. The scans revealed that 74 percent of the patients had at least one positive lesion in at least one body region. Local recurrence or metastasis of prostate cancer was confirmed in an estimated 91 percent of cases with positive Ga PSMA-11 PET readings. Researchers reported high positive predictive value, detection rate, and interreader agreement.

"Because the PSMA PET scan has proven to be more effective in

locating these tumors, it should become the new standard of care for men who have prostate cancer, for initial staging or localization of recurrence," Jeremie Calais, M.D., of the David Geffen School of Medicine at UCLA, said in a statement.

The FDA notes that no serious adverse reactions were attributed to Ga 68 PSMA-11. The most common adverse reactions were nausea, diarrhea, and dizziness. Misdiagnosis is also a risk with Ga 68 PSMA-11 because binding may occur in other types of cancers and with certain nonmalignant processes that could lead to image interpretation errors.

More information: More Information