FDA APPROVES NEW DIAGNOSTIC IMAGING AGENT TO DETECT RECURRENT PROSTATE CANCER

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The U.S. Food and Drug Administration today approved Axumin, a radioactive diagnostic agent for injection. Axumin is indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated prostate specific antigen (PSA) levels following prior treatment.

Prostate cancer is the second leading cause of death from cancer in U.S. men. In patients with suspected cancer recurrence after primary treatment, accurate staging is an important objective in improving management and outcomes.

“Imaging tests are not able to determine the location of the recurrent prostate cancer when the PSA is at very low levels,” said Libero Marzella, M.D., Ph.D., director of the Division of Medical Imaging Products in the FDA’s Center for Drug Evaluation and Research. “Axumin is shown to provide another accurate imaging approach for these patients.”

Two studies evaluated the safety and efficacy of Axumin for imaging prostate cancer in patients with recurrent disease. The first compared 105 Axumin scans in men with suspected recurrence of prostate cancer to the histopathology (the study of tissue changes caused by disease) obtained by prostate biopsy and by biopsies of suspicious imaged lesions. Radiologists onsite read the scans initially; subsequently, three independent radiologists read the same scans in a blinded study.

The second study evaluated the agreement between 96 Axumin and C11 choline (an approved PET scan imaging test) scans in patients with median PSA values of 1.44 ng/mL. Radiologists on-site read the scans, and the same three independent radiologists who read the scans in the first study read the Axumin scans in this second blinded study. The results of the independent scan readings were generally consistent with one another, and confirmed the results of the onsite scan readings. Both studies supported the safety and efficacy of Axumin for imaging prostate cancer in men with elevated PSA levels following prior treatment.

Axumin is a radioactive drug and should be handled with appropriate safety measures to minimize radiation exposure to patients and healthcare providers during

administration. Image interpretation errors can occur with Axumin PET imaging. A negative image does not rule out the presence of recurrent prostate cancer and a positive image does

not confirm the presence of recurrent prostate cancer. Clinical correlation, which may include histopathological evaluation of the suspected recurrence site, is recommended.

The most commonly reported adverse reactions in patients are injection site pain, redness, and a metallic taste in the mouth.
Axumin is marketed by Blue Earth Diagnostics, Ltd., Oxford, United Kingdom.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.