FDA approves new drug for advanced prostate cancer

Xofigo approved three months ahead of schedule under priority review program

The U.S. Food and Drug Administration today approved Xofigo (radium Ra 223 dichloride) to treat men with symptomatic late-stage (metastatic) castration-resistant prostate cancer that has spread to bones but not to other organs. It is intended for men whose cancer has spread after receiving medical or surgical therapy to lower testosterone.

Prostate cancer forms in a gland in the male reproductive system found below the bladder and in front of the rectum. The male sex hormone testosterone stimulates the prostate tumors to grow. According to the National Cancer Institute, an estimated 238,590 men will be diagnosed with prostate cancer and 29,720 will die from the disease in 2013.

Xofigo is being approved more than three months ahead of the product's prescription drug user fee goal date of Aug. 14, 2013, the date the agency was scheduled to complete review of the drug application. The FDA reviewed Xofigo under the agency's priority review program, which provides for an expedited review of drugs that appear to provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to marketed products.

"Xofigo binds with minerals in the bone to deliver radiation directly to bone tumors, limiting the damage to the surrounding normal tissues," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Xofigo is the second prostate cancer drug approved by the FDA in the past year that demonstrates an ability to extend the survival of men with metastatic prostate cancer."

In August 2012, the FDA approved Xtandi to treat men with metastatic castration-resistant prostate cancer that has spread or recurred, even with medical or surgical therapy to minimize testosterone. Xtandi is approved for patients who have previously been treated the chemotherapy drug docetaxel.

Xofigo's safety and effectiveness were evaluated in a single clinical trial of 809 men with symptomatic castration-resistant prostate cancer that spread to bones but not to other organs. Patients were randomly assigned to receive Xofigo or a placebo plus best standard of care.

The study was designed to measure overall survival. Results from a pre-planned interim analysis showed men receiving Xofigo lived a median of 14 months compared to a median of 11.2 months for men receiving placebo. An exploratory updated analysis conducted later in the trial confirmed Xofigo's ability to extend overall survival.

The most common side effects reported during clinical trials in men receiving Xofigo were nausea, diarrhea, vomiting and swelling of the leg, ankle or foot. The most common abnormalities detected during blood testing included low levels of red blood cells (anemia), lymphocytes (lymphocytopenia), white blood cells (leukopenia), platelets (thrombocytopenia) and infection-fighting white blood cells (neutropenia).

Xofigo is marketed by Wayne, N.J.-based Bayer Pharmaceuticals. Xtandi is co-marketed by Astellas Pharma U.S., Inc. of Northbrook, Ill., and Medivation, Inc. of San Francisco, Calif.

For more information:

- FDA: Office of Hematology and Oncology Products
- FDA: Approved Drugs: Questions and Answers
- FDA: Drug Innovation
- NCI: Prostate Cancer

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.

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