**Beat: Miscellaneous**

# FDA approves new drug to treat prostate cancer

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**USPA News -** The United States Food and Drug Administration (FDA) on Wednesday approved a new drug to treat men with symptomatic late-stage prostate cancer. Xofigo (radium Ra 223 dichloride) specifically targets those suffering from 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. Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA`s Center for Drug Evaluation and Research said Xofigo binds with minerals in the bone to deliver radiation directly to bone tumors, limiting the damage to the surrounding normal tissues. 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. "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," said Pazdur. The FDA, in August 2012, had previously 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, meanwhile, is being approved more than three months ahead of the product`s prescription drug user fee goal date of August 14, the date the agency was scheduled to complete review of the drug application. 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.

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