Tulane major player in FDA approval of new drug for advanced prostate cancer

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Patients fighting prostate cancer have a new treatment option on the market this month thanks in part to a major clinical trial led by Tulane University cancer specialist Dr. Oliver Sartor.

The U.S. Food & Drug Administration recently approved radium-223 dichloride (XofigoÂ®) for the treatment of men with symptomatic, bone-metastatic, castration-resistant prostate cancer that has spread to the bones but not other organs.

“This is an important addition to the treatment of advanced prostate cancer,” said Sartor, Tulane Cancer Center medical director and North American principal investigator for the pivotal phase III clinical trial of the drug. “It is immensely satisfying to be part of something that helps move medicine forward and provides new treatments to those who need it most.”

Patients from Seattle to Florida were treated at Tulane, which was the leading trial site in North America. The trial involved a total 921 patients in more than 100 centers in 19 countries who were randomly assigned to radium-223 or a placebo plus best standard of care.

“Most men with castration-resistant prostate cancer develop bone metastases, which can decrease overall survival,” Sartor said.

Radium-223 is an alpha particle-emitting radioactive therapeutic agent that seeks out regions of the bone affected by metastatic tumors. This allows delivery of radiation directly to tumors and limits damage to the surrounding normal tissues. It is administered via injection. Trial results showed that men receiving radium-223 lived a median of 14.9 months compared to a median of 11.3 months for those receiving a placebo.

Radium-223 was approved more than three months ahead of schedule under the FDA"s priority review program, which expedites the review of drugs that appear to provide safe and effective therapy when no satisfactory alternative exists, or offer significant improvement compared to existing treatments.

The commercial production of radium-223 is being co-marketed by Bayer and Algeta.