

Tulane Cancer Center To Begin Novel Clinical Trial for Late-Stage Prostate Cancer Drug

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International prostate cancer expert Dr. Oliver Sartor of Tulane Cancer Center is the first oncologist in the United States to offer patients an experimental new treatment for late-stage prostate cancer through a multi-center clinical trial that is currently recruiting patients at 100 sites across 20 countries worldwide.

The Cancer Center is seeking patients with advanced prostate cancer that has spread to the bones to take part in a phase III randomized clinical trial for Alpharadin (pronounced "Alpha-raydin"), an injectable treatment based on the radioactive substance Radium-223, an alpha-particle emitting pharmaceutical. All participants will receive the best available standard therapy and are randomized so that two-thirds of the subjects receive Alpharadin in addition. The other third of subjects will receive placebo along with the standard of care therapy. Early clinical trials of Alpharadin have suggested that it is well tolerated and that it might prolong survival for men whose prostate cancer is no longer responding to hormone therapy and has spread to the bones.

"Alpharadin appears to work by targeting and destroying cancer cells in the bone while sparing healthy bone marrow tissue," said Sartor, Piltz Professor of Cancer Research in the Departments of Medicine and Urology at Tulane University School of Medicine. "If successful in clinical trials, this compound could make a significant difference for the large number of men whose cancer has spread to the bones. Patients most often die as a consequence of the metastases — not the primary cancer — so preventing cancer from spreading and controlling cancer that has spread is a major clinical challenge."

According to the American Cancer Society, prostate cancer is the most frequently diagnosed cancer in men in the United States, affecting approximately one in six men each year; approximately 192,000 new cases will be diagnosed in 2009. Approximately 27,000 men in the United States die from prostate cancer each year

and about 90 percent of these men have bone metastases.

Treatment options for men with metastatic prostate cancer of the bones are limited, and life expectancy, if left untreated, is an average 12 to 18 months. In addition, bone metastases can be very debilitating. Typically, patients with bone metastases experience severe bone pain, which increases as the metastasis grows, as well as other serious complications including neurological symptoms, fractures, severe anemia, or spinal cord compression. These complications can decrease patient quality of life and shorten life expectancy.

Physicians and patients interested in learning more about this phase III clinical trial can contact the Cancer Center at 504-988-7869 or e-mail Sartor directly at osartor@tulane.edu for more information or to find out how eligible patients can enroll in the study.

The trial is being sponsored by Algeta, a Norwegian cancer therapeutics company in partnership with the German pharmaceutical company, Bayer Schering Pharma AG .