

Jan. 18, 2007

For immediate release

Prostate cancer clinical trial closes early

ANN ARBOR, Mich. - The Southwest Oncology Group, a national cancer research consortium, has closed one of its trials because of an unexpected pattern of late side effects. The trial, S9921, was testing a new treatment for poor risk prostate cancer.

A preliminary study in the United Kingdom had previously suggested the addition of the chemotherapy drug mitoxantrone to a treatment of two years of hormone deprivation would improve survival for men with poor risk prostate cancer after surgery to remove the prostate. "Poor risk" prostate cancer means the cancer has spread to the tissues adjacent to the prostate or has unfavorable appearances under a microscope that are linked to a high risk of the cancer returning after standard surgery or radiation therapy.

To test whether this approach was safe and effective, the Southwest Oncology Group initiated a randomized clinical trial in the year 2000. Patients were randomly assigned to receive hormone deprivation therapy alone or hormone deprivation therapy along with six doses of mitoxantrone. Mitoxantrone had initially been selected due to approval for advanced prostate cancer with an acceptable side effect profile in prior clinical trials. To date, 983 patients have been enrolled in the Southwest Oncology Group trial from 111 institutions and 235 investigators across the country. Of those enrolled, 488 participants received mitoxantrone as part of their treatment.

In a recent review of side effects and survival among study participants, the investigators leading the trial noted three cases of acute leukemia among the 488 patients who had received mitoxantrone. No patients in the hormone deprivation-only group developed leukemia, suggesting an increased potential risk of leukemia from mitoxantrone in this setting. Following a review and recommendation from the Southwest Oncology Group's Data Safety Monitoring Committee, the trial was closed.

"While it is recognized that these are only three isolated cases, the Southwest Oncology Group believes it is in the interest of patient safety to close the trial and monitor the patients for evidence of any unexpected late effects," says lead investigator L. Michael Glode, M.D., of the University of Colorado, "Of importance, this possible increase in risk would not have been identified so early without a randomized clinical trial that allowed comparison between a group receiving standard treatment and a group receiving a novel therapy approach."

Laurence Baker, D.O., Southwest Oncology Group Chairman, comments, "The whole Southwest Oncology Group is profoundly empathetic to the patients and their families that developed leukemia as a potential result of participating with this clinical trial."

The Southwest Oncology Group is one of the largest cancer clinical trials cooperative groups in the United States. Funded by research grants from the National Cancer Institute, the Group conducts clinical trials to prevent and treat cancer in adults, and to improve the life of cancer survivors. The Group's network consists of more than 5,000 physician-researchers practicing at nearly 550 institutions, including university hospitals and community cancer clinics.

Doctors have been informed to notify their patients who are enrolled in the trial immediately of the reasoning for the closure of this trial. Patients are directed to discuss concerns with their treating oncologist. The Southwest Oncology Group Headquarters in Ann Arbor, Mich., can be contacted by calling 734-998-7140.

###