Treatment with Radiotherapy, Androgen Suppression Therapy, and Docetaxel Improves Cancer Control in Men at High Risk for Prostate Cancer Recurrence After Prostatectomy

San Francisco—Patients at high risk for prostate cancer recurrence after radical prostatectomy (RP) and adjuvant radiotherapy (RT) realize significantly improved cancer control with the addition of systemic androgen suppression therapy (AST) and docetaxel chemotherapy as compared with historical controls according to results of the Radiation Therapy Oncology Group (RTOG) 0621 clinical trial presented at the American Society for Radiation Oncology 56th Annual Meeting, in San Francisco.

"Although adjuvant radiotherapy benefits many patients with prostate cancer, some patients remain at high risk for cancer progression and death from the disease despite undergoing radical prostatectomy and post-operative radiotherapy, says RTOG 0621 trial Principal Investigator Mark D. Hurwitz, M.D., vice-chair for Quality, Safety and Performance Excellence and director of Thermal Oncology in the Department of Radiation Oncology at Thomas Jefferson University in Philadelphia. "Our RTOG 0621 results analysis at 3 years follow-up shows patients' freedom from disease progression was improved more than 20 percent compared with historical levels by the addition of systemic therapy with AST and docetaxel."

RTOG, which now carries out research as NRG Oncology, conducted this trial with 74 enrolled patients eligible for analysis who met the high-risk eligibility criteria (post RP: prostate-specific antigen [PSA] nadir >0.2 ng/ml and Gleason score ≥7, or PSA nadir ≤0.2 ng/ml with Gleason score ≥8 and stage ≥pT3). Data from the phase III Southwest Oncology Group (SWOG) 8794 trial, which showed that patients with similar risk characteristics after RP and adjuvant RT had a 50 percent cancer-progression risk, established the control group for RTOG 0621. At 3 years follow-up, 73 percent of the RTOG 0621 patients had not experienced disease progression.

The combined therapy was also reported to be tolerated well by patients. Hurwitz suggests that the acute grade 3 and 4 hematologic toxicities experienced may be due to the initiation of chemotherapy 3 to 6 weeks after pelvic RT treatment; however, the most numerous toxicities were laboratory-defined and not associated with clinical manifestations. For example, the low rates of febrile neutropenia and infection were consistent with the use of docetaxal in other settings.

Hurwitz points out the RTOG 0621 results add to the growing appreciation for the effectiveness of docetaxel in the treatment of prostate cancer. He cites as an example the results presented at the American Society of Clinical Oncology 2014 Annual Meeting of the ECOG E3805 trial (ChemoHormonal Therapy Versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer), which showed a 13.6-month survival advantage with the addition of 6 cycles of docetaxel to AST for men newly diagnosed with metastatic prostate cancer. "The ECOG study results provided significant momentum for further study of the use of docetaxal in the treatment of early-stage
disease in RTOG 0621. What is particularly novel about our study is that it is the first multicenter trial to show a significant benefit—albeit a freedom from progression benefit versus an overall survival benefit—with chemotherapy in addition to radiation in nonmetastatic prostate cancer treatment," says Hurwitz.

Looking to future research for the high-risk prostate cancer population, Hurwitz points to the much-awaited RTOG 0521 phase III trial results that will report on the use of chemotherapy in combination with up-front radiation and ADT. "While the RTOG 0521 results are awaited, the phase II RTOG 0621 study of similar patients at high risk for recurrence postprostatectomy has shown an advantage that warrants development of a phase III trial in the postprostatectomy setting to complement the now-completed RTOG 0521 trial," concludes Hurwitz.

“NRG Oncology’s research in prostate cancer speaks to the strong collaboration that has occurred among the cooperative groups to advance treatment options especially for patients at high risk for poor outcomes. NRG Oncology looks forward to a continued spirit of collaboration within the National Clinical Trials Network,” says Walter J. Curran Jr, M.D., an NRG Oncology Group Chairman and Executive Director of the Winship Cancer Institute of Emory University in Atlanta.

This work was supported by RTOG grant U10 CA21661 and CCOP grant U10 CA37422 from the National Cancer Institute and by Sanofi-Aventis.

www.nrgoncology.org

NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of patients with cancer. Founded in 2012, NRG Oncology is a Pennsylvania-based nonprofit corporation that integrates the research strengths of the National Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group and the Gynecologic Oncology Group. The research organization seeks to carry clinical trials with emphases on gender-specific malignancies including gynecologic, breast, and prostate cancers and on localized or locally advanced cancers of all types. NRG Oncology’s extensive research organization is comprised of multidisciplinary investigators including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians and encompasses more than 1300 research sites located worldwide with predominance in the United States and Canada. NRG Oncology is supported primarily through grants from the National Cancer Institute (NCI) and is one of five research groups in the NCI’s National Clinical Trials Network.