For Immediate Release

Patients with Prostate Cancer at High Risk for Metastasis Live Longer When Chemotherapy is Added to the Standard Treatment Regimen of Radiotherapy and Hormonal Therapy

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Chicago, Ill, May 31, 2015—The initial results of a randomized phase III trial reported today at the 2015 American Society of Clinical Oncology Annual Meeting show that the addition of docetaxel chemotherapy (and prednisone) to standard treatment extends significantly the lives of men diagnosed with high-risk prostate cancer that has not spread outside the pelvic region. Risk was determined as the combination of Gleason score (a rating of how aggressive cancer cells appear microscopically), pretreatment prostate-specific androgen (PSA) level, and tumor stage.

The study analysis of RTOG 0521, initially conducted by the Radiation Therapy Oncology Group (RTOG), now conducting research as NRG Oncology, included 562 patients enrolled at sites across the United States and Canada, and in Australia. Patients were randomized to receive either the standard treatment (radiotherapy [RT] plus 2-year hormonal [androgen suppression] therapy) or the experimental treatment (RT, 2-year hormonal therapy plus docetaxel chemotherapy beginning 28 days after the completion of RT).

“Adjuvant chemotherapy had been shown to have an effective role in other high-incidence cancers, such as lung, breast, and colorectal. This led us to test the hypothesis that treating patients who, at initial diagnosis, are at the greatest risk of dying from prostate cancer with adjuvant chemotherapy early on would result in a survival benefit,” says lead abstract author and presenter Howard M. Sandler, MD, MS, FASTRO, the principal investigator of the RTOG 0521 trial, chair of the NRG Oncology Genitourinary Cancer Committee, and chair of radiation oncology at Cedars-Sinai Medical Center in Los Angeles.

Sandler reported, at a median follow-up of 5.5 years post trial enrollment, overall survival rates of 89 percent vs 93 percent, centrally reviewed deaths of 52 vs 36, and 5-year disease-free survival rates of 66 percent vs 73 percent for the standard treatment arm and the experimental treatment arm, respectively. He also noted the perplexing result of a reduction in deaths from both prostate cancer and non-prostate cancer-related causes in the experimental treatment arm. Adding chemotherapy after RT for this patient population was found to be acceptably safe. “These results come at a time of other evidence supporting the use of chemotherapy with docetaxel earlier in the disease process. Although this trial justifies the use of adjuvant docetaxel for select men with high-risk prostate cancer, I think that further follow-up would be beneficial for assessing the long-term impact of adjuvant chemotherapy,” says Sandler, who recommends that the use of docetaxel in this setting be an individualized decision made by the patient and his team of prostate cancer physicians.

“These trial results build on the NRG Oncology Genitourinary Cancer Committee’s long history of practice-changing research that has improved prostate cancer care significantly,” says Walter J. Curran, Jr, MD, an NRG Oncology Group Chairman and Executive Director of the Winship Cancer Institute of Emory University in Atlanta. The trial team is to be congratulated for this positive result and for completing the first phase III trial investigating adjuvant chemotherapy for high-risk prostate cancer.”
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Clinical Trial Information: NCT00288080

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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 world-wide 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.