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Anti-androgen Therapy in addition to Radiation Therapy Improves Long-term Survival for Men with Recurrent or Persistent Prostate Cancer

PHILADELPHIA, PA — NRG Oncology investigators found that daily bicalutamide during and for 24 months after salvage radiation therapy improved long-term survival for men with persistent or recurrent cancer following radical prostatectomy. The results of NRG Oncology's RTOG 9601, "Radiation with or without Antiandrogen Therapy in Recurrent Prostate Cancer" will be published in the *New England Journal of Medicine* on January 12, 2017.

A common treatment for men with localized prostatic cancer is radical prostatectomy, and at least 30% of the patients who undergo this surgery subsequently experience tumor recurrence. In an attempt to improve survival for these men, RTOG 9601 studied 760 post-prostatectomy patients with pathologic stage T3N0 or with pathologic stage T2N0 who also have had a positive surgical margin and with a detectable PSA levels between 0.2 and 4.0 ng/mL. These patients were randomly assigned to a double-blinded, placebo-controlled trial of radiation therapy with placebo or anti-androgen therapy during and after radiation therapy. The anti-androgen therapy included 150 mg of bicalutamide daily for 24 months. The median follow-up time for surviving patients is 13 years.

"Previous research has indicated that the combination of radiation and anti-androgen therapies could improve survival in some men with an intact prostate. NRG Oncology's RTOG 9601 evolved that concept and with this phase 3 trial evaluated whether this combination could result in the improvement of overall survival and metastasis-free survival for patients with post-operative recurrence," says William U. Shipley, MD, principal investigator and lead author of NRG-RTOG 9601 and radiation oncologist at the Massachusetts General Hospital and Harvard Medical School.

The outcome differences in NRG-RTOG 9601 are significant. The actuarial overall survival results at 12 years were 76.3% for the patients who received radiation therapy plus anti-androgen therapy and 71.3% for the patients who received radiation therapy plus placebo (hazard ratio 0.77 [95% CI:0.59-0.99], 2-sided p = 0.04). The twelve-year incidences of centrally reviewed prostate cancer deaths were 5.8% for the combined arm and 13.4% for the placebo arm. The cumulative incidence of metastatic prostate cancer at twelve years was 14.5% for the combined arm and 23.0% for the placebo arm. Late radiation-related adverse events were similar in both arms, however, gynecomastia was recorded in 69.9% of the anti-androgen therapy arm and 10.9% in the placebo arm.

"The results of this study will favorably impact treatment decision-making for men with localized prostatic cancer. The NRG Oncology researchers involved with NRG-RTOG 9601 have changed the standard of care for men who experience post-operative recurrence," stated Walter J. Curran, Jr., MD, NRG Oncology Group Chair and Executive Director of the Winship Cancer Institute of Emory University.

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Full Citation

Radiation with or without Antiandrogen Therapy in Recurrent Prostate Cancer

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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 of the National Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group, and the Gynecologic Oncology Group. The research organization seeks to carry out 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 comprises 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.