Promising Results for Bladder-Sparing Treatment of Muscle-Invasive Bladder Cancer Presented at the American Society for Radiation Oncology Annual Meeting

San Francisco—Results of a retrospective analysis of two clinical trials conducted by the Radiation Therapy Oncology Group (RTOG), which now carries out research as NRG Oncology, show that patients with muscle-invasive bladder cancer who—at the time of cystoscopic evaluation between the induction and consolidation phases of chemoradiotherapy—were determined to have small amount of superficial (Ta or Tis) disease do just as well continuing with the bladder preservation treatment as those patients who were determined to have a complete response to the induction chemoradiotherapy.

Historically, patients determined to have less than a complete response when evaluated after induction chemoradiotherapy would go on to immediate bladder removal surgery (cystectomy). However, the RTOG 99-06 and RTOG 0233 trials allowed for patients with small amount of superficial disease (Ta or Tis) to continue with the consolidation chemoradiotherapy and avoid immediate cystectomy. The purpose of the pooled analysis, presented by lead investigator Timur Mitin, MD, PhD, an assistant professor in the Department of Radiation Medicine at Oregon Health & Science University, in Portland, was to determine whether it was an appropriate change in clinical practice or whether these patients had worse outcomes compared to those with complete response.

“We found the decision was appropriate as there is no apparent difference in either bladder cancer recurrence or future salvage cystectomy rates between patients who had a complete versus near-complete response as judged at the time of cystoscopic evaluation after the induction phase of bladder-reserving, combined-modality therapy,” says Mitin. “These results are important for centers that offer bladder-sparring trimodality therapy, as they clarify how to manage the population of patients with near-complete response after the induction phase and support the clinical decision to proceed with bladder preservation.”

Of the 119 total cases eligible for analysis, 101 patients had a complete response and 18 patients a near complete response. There was no difference in overall survival, disease free survival, and bladder cancer recurrence free survival between these two groups.

Also presented at ASTRO were the initial results of RTOG 0524 a phase I/II clinical trial that evaluates bladder-sparing chemoradiotherapy as a treatment approach for patients with muscle-invasive bladder cancer who, due to additional illness, advanced age, or personal preference are not candidates for cystectomy. This is the first RTOG-led study evaluating a bladder-sparing approach in this patient population.

“Given the overall success of bladder-preservation therapy in RTOG trials, we hypothesized that nonsurgical treatments can safely be offered to these poor-risk patients with a reasonable chance for success,” says NRG Oncology investigator and presenter Huong T. Pham, MD, a radiation oncologist at Virginia Mason Medical Center in
Seattle, Wash. While most patients experienced some treatment toxicity, approximately two-thirds of the side effects resolved after 7 days post treatment which Pham reports was anticipated.

RTOG 0524 is also the first study to evaluate the use of the agent trastuzumab (Herceptin®) with paclitaxel-based, non-cisplatin chemoradiotherapy for patients with muscle-invasive bladder cancer whose tumor shows overexpression of the human epidermal growth factor receptor-2 (Her-2/neu). Trial participants in arm 1 (21 cases with tumor Her-2/neu overexpression) received chemoradiotherapy and trastuzumab and participants in arm 2 (47 cases with no tumor overexpression) received chemoradiotherapy alone. “The targeting of Her2/neu in patients with overexpressing tumors remains investigational though promising,” says Pham.

“For patients with bladder cancer to maintain intact and well-functioning bladders post treatment has enormous quality of life ramifications. NRG Oncology has been a leader in the area of bladder-sparing treatment and intends to continue the effort to bring this option to more patients in the future,” says Walter J. Curran, Jr, MD, an NRG Oncology Group Chairman and Executive Director of the Winship Cancer Institute of Emory University in Atlanta.

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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.