A shorter radiation therapy schedule can be as effective as a conventional schedule for men with low-risk prostate cancer

*RTOG 0415 data indicates treatment delivered over five and one-half weeks results in similar disease-free survival rates as an eight-week schedule*

San Antonio, October 19, 2015— Hypofractionated radiation therapy (RT), which is delivered in larger doses over a shorter time period than conventional RT, results in similar rates of cure and side effects compared to a longer treatment schedule for some men with low-risk prostate cancer, according to research presented today at the American Society for Radiation Oncology’s (ASTRO’s) 57th Annual Meeting.

*RTOG 0415 was a phase III study conducted from April 2006 to December 2009 across the U.S. and Canada that compared the five-year disease-free survival (DFS) rate of 1,115 men with low-risk prostate cancer. DFS refers to the length of time after the primary treatment for cancer ends that a patient survives without any signs or symptoms of the cancer. Patients in the trial were randomly assigned to receive either hypofractionated RT or a conventional RT schedule. Baseline characteristics were similar between the two groups, including the patients’ age (median age 65) and pretreatment prostate specific antigen (PSA) scores (median PSA = 5.4 ng/mL).*
The primary purpose of the study was to determine if hypofractionated RT results in five-year DFS that is not lower than conventional RT by more than seven percent. The study also looked at overall survival (OS) rates and patients’ biochemical recurrence (which is a rise in PSA levels following treatment).

A total of 1,105 men qualified for the study protocol and were randomized to two groups: conventional RT, consisting of 73.8 Gy in 41 fractions delivered over 8.2 weeks was administered to 547 of the men, while 554 men received hypofractionated RT, consisting of 70 Gy in 28 fractions delivered over 5.6 weeks. At a median follow-up of 5.9 years, the results demonstrated that hypofractionated RT results in similar disease-free survival, as compared to conventional RT for men with low-risk prostate cancer. It is estimated that seven-year disease-free survival rates is 76 percent for patients assigned to conventional RT, and 82 percent for patients assigned to hypofractionated RT.

Comparison of biochemical recurrence and overall survival also met protocol non-inferiority criteria. Additionally, both groups reported a similar rate of Grade 3 late side effects. Of the patients who received conventional RT, 3 percent had gastrointestinal side effects and 5 percent had genitourinary (relating to the genital and urinary organ) side effects, compared to 5 percent of the patients in the hypofractionated RT group who had gastrointestinal side effects and 6 percent who reported genitourinary side effects.

“The results of our study demonstrate that for men with low-risk prostate cancer, hypofractionated radiation therapy offers a shorter, more convenient treatment schedule without compromising cure or causing additional side effects,” said lead author of the study W. Robert Lee, MD, MS, MEd, professor in the Department of Radiation Oncology at Duke University School of Medicine.

“This is the first large-scale, randomized study demonstrating the value of a shorter course of radiation therapy for low-risk prostate cancer patients,” said Howard Sandler, MD, MS, FASTRO, co-author of the study and professor and chair of the department of radiation oncology, Cedars Sinai Medical Center. “The results are not surprising, however, given that studies on the effects of
hypofractionated radiation therapy in patients with early stage breast cancer, which is similar to early stage prostate cancer, have demonstrated similar outcomes.”

The abstract, “NRG Oncology RTOG 0415: A Randomized Phase III Non-Inferiority Study Comparing 2 Fractionation Schedules in Patients with Low-Risk Prostate Cancer” will be presented in detail during the Plenary session at ASTRO’s 57th Annual Meeting at 2:15 p.m. Central time on Monday, October 19, 2015. To speak with Dr. Sandler, please call Nancy Mayes in ASTRO’s Press Office at the Henry B. González Convention Center in San Antonio on October 18 – 21, 2015 at 210-258-8104 or 210-258-8105, or email press@astro.org.

ASTRO’s 57th Annual Meeting, being held at the Henry B. González Convention Center in San Antonio, October 18-21, 2015, is the nation’s premier scientific meeting in radiation oncology. The 2015 Annual Meeting is expected to attract more than 11,000 attendees including oncologists from all disciplines, medical physicists, dosimetrists, radiation therapists, radiation oncology nurses and nurse practitioners, biologists, physician assistants, practice administrators, industry representatives and other health care professionals from around the world. Led by ASTRO President Bruce D. Minsky, MD, FASTRO, a radiation oncologist specializing in gastrointestinal cancers, Professor of Radiation Oncology, and the Frank T. McGraw Memorial Chair at The University of Texas MD Anderson Cancer Center, Houston, the theme of the 2015 Meeting is “Technology Meets Patient Care.” Dr. Minsky’s Presidential Symposium, “Multidisciplinary Management of Esophageal and Rectal Cancers,” will feature Leonard L. Gunderson, MD, MS, FASTRO, and Joel E. Tepper, MD, FASTRO, to highlight imaging, staging, genomics and data mining approaches, as well as the latest advances in esophageal and colorectal cancer treatment. ASTRO’s four-day scientific meeting includes presentation of more than 2,100 abstracts: five plenary papers, 351 oral presentations, 1,609 posters and 171 digital posters in more than 53 educational sessions and 26 scientific panels for 20 disease-site tracks. Three keynote speakers will address a range of topics including cancer biology in radiation oncology, the essential roles of a physician, and patient safety: Arul Chinnaiyan, MD, PhD, Professor and Director, Michigan Center for Translational Pathology; Francisco G. Cigarroa, MD, Past
President and Chancellor, University of Texas; and Gerald B. Hickson, MD, Senior Vice President and Assistant Vice Chancellor, Vanderbilt University Medical Center.

ABOUT ASTRO

ASTRO is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals that specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, the Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes three medical journals, International Journal of Radiation Oncology • Biology • Physics (www.redjournal.org), Practical Radiation Oncology (www.practicalradonc.org) and Advances in Radiation Oncology (www.advancesradonc.org); developed and maintains an extensive patient website, www.rtanswers.org; and created the Radiation Oncology Institute (www.roinstitute.org), a non-profit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment. To learn more about ASTRO, visit www.astro.org.

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NRG Oncology RTOG 0415: A Randomized Phase III Non-Inferiority Study Comparing 2 Fractionation Schedules in Patients with Low-Risk Prostate Cancer

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Purpose/Objective(s): To determine whether the efficacy of a hypofractionated (H) schedule is no worse than a conventional (C) schedule in men with low-risk prostate cancer.

Materials/Methods: The trial opened to accrual in April 2006 and closed in December 2009. One thousand one hundred fifteen men with low-risk prostate cancer (clinical stage T1-2a, Gleason ≤6, PSA <10) were randomly assigned 1:1 to a conventional (C) schedule (73.8 Gy in 41 fractions over 8.2 weeks) or to a hypofractionated (H) schedule (70 Gy in 28 fractions over 5.6 weeks). The trial was designed to establish with 90% power and alpha = 0.05 that (H) results in 5-year disease-free survival (DFS) that is not lower than (C) by more than 7% (hazard ratio (HR) < 1.52). Secondary endpoints reported include: freedom from biochemical recurrence (FFBR), and overall survival. At the third planned interim analysis (July 2015), the NRG Oncology Data Monitoring Committee recommended that the results of the trial be reported.

Results: One thousand and one protocol eligible men were randomized: 547 to C and 554 to H. Median follow-up is 5.9 years. Baseline characteristics were not different according to treatment arm. Median age = 65 yrs; median pretreatment PSA = 5.4 ng/mL. At the time of analysis there were 185 DFS events; 99 in the C arm and 86 in the H arm. The estimated seven-year disease-free survival is 75.6% (95% CI 70.3, 80.1) in the C arm and 81.8% (77.5, 85.3) in the H arm. The DFS HR (C/H) is 0.85 (0.64, 1.14). Comparison of biochemical recurrence (HR = 0.77, (0.51, 1.17)) and overall survival (HR = 0.95, (0.65, 1.41)) also met protocol non-inferiority criteria. Grade ≥ 3 GI toxicity is 3.0% (C) vs. 4.6% (H), Relative risk (RR) for H vs. C 1.53, (95% CI 0.86,2.37); grade ≥ 3 GU toxicity is 4.5% (C) vs. 6.4% (H), RR = 1.43 (0.86,2.37).

Conclusion: In men with low-risk prostate cancer, 70 Gy in 28 fractions over 5.6 weeks is non-inferior to 73.8 Gy in 41 fractions over 8.2 weeks. (ClinicalTrials.gov identifier: NCT00331773)

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