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News Release

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Press Room in Atlanta
September 22-25
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Long-term hormonal therapy in intermediate-risk prostate cancer patients does not improve overall survival

Analysis of patient subset from RTOG 9202

Atlanta, September 23, 2013—A secondary analysis of the historic RTOG 9202 prostate cancer trial examined results of men with intermediate-risk prostate cancer who had received long-term hormonal therapy after radiation therapy, and concluded that there were no additional benefits when compared to short-term hormonal therapy, according to research presented today at the American Society for Radiation Oncology's (ASTRO's) 55th Annual Meeting.

Men with advanced prostate cancer typically receive hormonal therapy to reduce the level of androgens, or male hormones, in their bodies. Although hormone therapy alone will not cure prostate cancer, lowering androgen levels can reduce prostate tumors size or stall their growth.

The original RTOG 9202 trial (Hanks 2003) evaluated the potential benefits of long-term adjuvant androgen deprivation (LTAD) for two years after initial androgen deprivation, when compared to short-term (initial) androgen therapy (STAD) in mostly high-risk prostate cancer patients receiving external beam radiation therapy (EBRT). Because some intermediate-risk prostate cancer patients were included in the study, a current analysis was conducted to determine if patients in the intermediate-risk subset experienced an additional survival benefit with LTAD.

Researchers reviewed all patients enrolled in RTOG 9202 categorized with intermediate-risk prostate cancer with T2 disease (tumor confined to the prostate), a Prostate Specific Antigen (PSA) of < 10 and a Gleason Score of 7; or, who were immediate-risk prostate cancer patients with T2 disease, PSA of 10-20 and a Gleason Score < 7. A total of 133 patients were analyzed. The LTAD group consisted of 59 patients, and the STAD group consisted of 74 patients. Statistical analysis was used to determine Overall Survival (OS), Disease Specific Survival (DSS) and PSA Failure rates (PSAF), and the median follow-up was more than 11 years. There was no statistical difference in OS with 10-year estimates of 61 percent for the STAD group and 65 percent for the LTAD group. DSS was found to be 96 percent in both groups. PSAF occurred in 38 patients in the STAD group and in 33 in the LTAD group. Ten-year PSAF rates were 53 percent for the STAD group and 55 percent for the LTAD group (p=.99).

"Most clinicians have felt that 'more was better' when it came to blocking testosterone in prostate cancer patients, however, results for the specific endpoints we focused on, OS and DSS, indicate that this was clearly not the case," said Amin Mirhadi, MD, lead author of the study and a radiation oncologist at Cedars-Sinai Medical Center in Los Angeles. "This data supports administering less treatment, which will result in fewer side effects and reduce patients' overall health care costs."

The abstract, "Effect of Long-Term Hormonal Therapy (vs. Short-Term Hormonal Therapy): A Secondary Analysis of Intermediate Risk Prostate Cancer Patients Treated on RTOG 9202," will be presented in detail in a scientific session at ASTRO's Annual Meeting at 10:45 a.m. Eastern time, on Monday, September 23, 2013. To speak with Dr. Mirhadi, call Michelle Kirkwood on September 22—25, 2013, in the ASTRO Press Office at the Georgia World Congress Center in Atlanta at 404-222-5303 or 404-222-5304, or email michellek@astro.org.

ASTRO's 55th Annual Meeting, held in Atlanta, September 22—25, 2013, is the premier scientific meeting in radiation oncology and brings together 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. The theme of the 2013 meeting is "Patients: Hope • Guide • Heal" and will focus on patient-centered care and the importance of the physician's role in improving patient-reported outcomes and the quality and safety of patient care. The four-day scientific meeting includes presentation of four plenary papers, 363 oral presentations, 1,460 posters and 144 digital posters in 70 educational sessions and scientific panels for 19 disease sites/tracks. Keynote and featured speakers include: William B. Munier, director of the Center for Quality Improvement and Patient Safety at the Agency for Healthcare Research and Quality; Darrell G. Kirch, MD, president and CEO of the Association of American Medical Colleges; James Cosgrove, PhD, director of the U.S. Government Accountability Office; Otis W. Brawley, MD, chief medical officer of the American Cancer Society; and Peter Friedl, MD, PhD, of St. Radboud University Nijmegen Medical Centre at the University of Nijmegen and MD Anderson Cancer 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 two medical journals, International Journal of Radiation Oncology • Biology • Physics (www.redjournal.org) and Practical Radiation Oncology (www.practicalradonc.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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2013 American Society for Radiation Oncology (ASTRO) 55th Annual Meeting
News Briefing, Wednesday, September 25, 2013, 8:15 a.m. Eastern time

Scientific Session: Monday, September 23, 2013, 10:45 a.m. - 12:15 p.m. ET, Georgia World Congress Center

61 Effect of Long-Term Hormonal Therapy (vs. Short-Term Hormonal Therapy): A Secondary Analysis of Intermediate Risk Prostate Cancer Patients Treated on RTOG 9202

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Purpose/Objective(s): RTOG 9202 was a randomized trial testing long-term adjuvant androgen deprivation (LTAD) after initial androgen deprivation vs initial androgen deprivation only (STAD) with EBRT in patients with mostly high-risk prostate cancer. Of interest, some intermediate risk patients were eligible**.** RTOG 9202 demonstrated a benefit in all study endpoints except OS, with the exception of the subset of patients with Gleason score 8-10. More recently, RTOG 9408 found an OS advantage in patients with T1b-T2b prostate CA with PSA less than 20, with the bulk of the benefit observed among intermediate risk patients. Thus, while STAD was validated in 9408, it is not known whether patients in the intermediate risk subset would experience an additional survival benefit with longer duration androgen deprivation. The inclusion of some intermediate risk patients in 9202 allowed us to explore whether LTAD had any incremental benefit above STAD.
Materials/Methods: An analysis was done of all patients enrolled in RTOG 9202 who were defined as int-risk disease based on having T2 disease and PSA<10 and Gleason=7 OR T2 disease and PSA 10-20 and Gleason <7. This review yielded a total of 133 patients who fit this definition: 74 in the STAD arm and 59 in the LTAD arm. The Kaplan-Meier was used to determine OS, with the log-rank test used to test for the endpoint of OS. The cumulative incidence approach was used to estimate the rate DSS, with Gray's test used to test the significance between two treatment arms for the endpoint of DSS. Two-sided test was used at a significance level 0.05.
Results: With over 11 years of median follow up, 39 patients were alive in the STAD group and 33 were alive in the LTAD group. There was no difference in OS (10-year estimates 61% STAD vs. 65% LTAD, p=0.53) between the two groups. With regards to DSS, there were a total of only 4 failures in the STAD group and 3 in the LTAD group. 10-year DSS was 96% vs. 96%%, respectively, p=0.72. PSAF occurred in 38 patients in the STAD group and 33 in the LTAD group. 10-year PSAF rates were 53% and 55%, respectively, p=0.99.
Conclusions: LTAD did not confer a benefit in terms of OS, DSS and PSAF in the subset of patients analyzed. RTOG 9202 included a subset of patients with intermediate-risk prostate cancer and this allowed us to explore whether hormonal therapy duration beyond short-term use could potentially have resulted in an additional survival benefit. While the subset was relatively small, the treatment assignment was randomly applied and a trend in favor of longer hormonal therapy would have been of interest. Given the small number of disease-specific deaths observed and the lack of a benefit with respect to any of our endpoints, this secondary analysis does not suggest that exploration of longer duration hormonal therapy is worth testing in this intermediate-risk subset.

Author Disclosure Block: A.J. Mirhadi: None. **D. Hunt:** None. **G.E. Hanks:** None. **C.A. Peters:** None. **K.L. Zeitzer:** None. **D.P. D'Souza:** None. **C.A. Lawton:** None. **H.M. Sandler:** G. Consultant; Astellas.