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News Release

Embargoed until 11:00 a.m. PT, Monday, September 15, 2014

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Press Office in San Francisco
September 14-17
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Patient reported data indicates that single fraction radiation therapy is as effective as multiple fraction radiation therapy for patients with bone metastases in a broad clinical setting

San Francisco, September 15, 2014—A prospective study that compared patient-reported outcomes of a broad set of cancer patients with bone metastases demonstrates that single fraction radiation therapy (SFRT) is equally as effective as multiple fraction radiation therapy (MFRT) when pain, function and quality of life are considered, according to research presented today at the American Society for Radiation Oncology's (ASTRO's) 56th Annual Meeting. The multi-center study indicates that improvements in patients' pain, function and degree of distress were similar between the SFRT and MFRT patients, including for the type of patients who were excluded from previous clinical trials, thus confirming the validity of prior randomized control trials to real-world practice.

All six centers at The BC Cancer Agency in British Columbia, Canada, participated in the study from May to December 2013. A total of 648 patients with bone metastases were evaluated (updated data), including 226 (35 percent) with metastases complicated by fracture or neurological compromise such as spinal cord compression. The mean patient age at diagnosis was 65 years, and 54 percent of the patients were male. Patients received SFRT or MFRT at the discretion of the treating oncologist, with 56 percent (363) receiving SFRT; and 44 percent (285) receiving MFRT. The three most common primary bone metastases sites were

genitourinary (31 percent), lung (22 percent) and breast (22 percent), with the spine being the most common site treated (44 percent).

Patients completed both the pre- and post-radiation therapy (RT) questionnaires. The three-question assessments were standardized and designed to measure patients' perception of pain, function and quality of life using a non-dichotomous, ordinal, five-point scale. Patients were asked to rate, on a 0 to 4-point scale (with zero being "not at all" and four being "very much,") the degree of their bone pain; the degree to which the pain interfered with their ability to care for themselves; and their level of frustration with their bone pain.

A multivariable regression analysis of the patient surveys pre- and post-treatment was performed. Comparisons were made between patients who received SFRT versus MFRT. Whether treated with SFRT or MFRT, patients in the broad clinical practice setting (i.e. not a clinical trial) reported similar pain, function and quality of life. There were no significant differences in changes in mean patient-reported outcome scores for SFRT patients versus MFRT patients—pain: 1.29 vs. 1.17 point improvement, respectively (p=0.24); function: 0.80 vs. 0.95 point improvement, (p=0.17); or degree of symptom distress: 1.26 vs. 1.26 point improvement, (p=0.98). Furthermore, the proportion of patients with a partial pain response was similar for patients who receive SFRT versus MFRT (73% versus 73%; p = 0.93) as well as the proportion with a complete pain response (19% versus 22%; p = 0.31).

"Previous research has shown that SFRT is equally effective as more costly and inconvenient MFRT courses for patients with painful bone metastases, however, these studies have been generally limited to well-controlled clinical trials, where many patients are excluded, such as those with poor performance status, fractures or neurological damage," said lead study author Robert A. Olson, MD, MSc, the research and clinical trials lead and a radiation oncologist at the BC Cancer Agency Centre for the North. "There is a very low utilization of SFRT for bone metastases worldwide, partially because oncologists are often reluctant to use SFRT for patients who do not meet the criteria of previous clinical trials. We wanted to determine if SFRT is equally effective as MFRT in the broad clinical practice setting, capturing all types of patients who receive RT for bone metastases. This study is ongoing, and to date, we have collected data from 648 patients who completed questions prior to and after RT. The results support the generalizability of prior randomized controlled trials to real-world practice, thus confirming that SFRT should be the standard management policy for patients with uncomplicated bone metastases. Further research is needed to confirm whether SFRT is also appropriate for complicated bone metastases, though our early results with a modest sample size suggest

SFRT may be appropriate in some circumstances. We are hopeful that this will lead to increased use of SFRT for bone metastases throughout the world and improved quality of life for these patients."

The abstract, "Patient Reported Outcomes on the Impact of Single versus Multiple Fraction Palliative Radiotherapy for Uncomplicated Bone Metastases on Pain, Function and Degree of Symptom Distress," will be presented in detail during a scientific session at ASTRO's 56th Annual Meeting at 2:45 p.m. Pacific time on Tuesday, September 16, 2014. To speak with Dr. Olson, please call Michelle Kirkwood on September 14 – 17, 2014, in the ASTRO Press Office at the Moscone Center in San Francisco at 415-978-3503 or 415-978-3504, or email michellek@astro.org.

ASTRO's 56th Annual Meeting, to be held at the Moscone Center in San Francisco, September 14-17, 2014, is the nation's premier scientific meeting in radiation oncology. The 2014 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 G. Haffty, MD, FASTRO, a radiation oncologist specializing in breast cancer, the theme of the 2014 Meeting is "Targeting Cancer: Technology and Biology," and the Presidential Symposium, "Local-regional Management of Breast Cancer: A Changing Paradigm," will feature Jay R. Harris, MD, FASTRO, and Thomas A. Buchholz, MD, FASTRO, to highlight recent practice-changing, landmark studies and current developments in the local-regional management of breast cancer. ASTRO's four-day scientific meeting includes presentation of up to four plenary papers, 360 oral presentations, 1,862 posters and 144 digital posters in more than 50 educational sessions and scientific panels for 20 disease-site tracks. Three keynote speakers will address a range of topics including oncologic imaging, biology and targeting in oncology, and human error and safety concerns: Hedvig Hricak, MD, PhD, Chair of the Department of Radiology and the Carroll and Milton Petrie Chair at Memorial Sloan Kettering Cancer Center; Frank McCormick, PhD, FRS, DSc (hon), Professor Emeritus and the David A. Wood Distinguished Professor of Tumor Biology and Cancer Research of the University of California at San Francisco Helen Diller Family Comprehensive Cancer Center; and Sidney Dekker, PhD, MA, MSc, Professor and Director of the Safety Science Innovation Lab at Griffith University, Brisbane, Australia.

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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2014 American Society for Radiation Oncology (ASTRO) 56th Annual Meeting
News Briefing, Monday, September 15, 2014, 11:00 a.m. Pacific time

Scientific Session: Tuesday, September 16, 2014, 2:45 – 4:15 p.m. PT, the Moscone Center

172 Patient Reported Outcomes on the Impact of Single versus Multiple Fraction Palliative Radiotherapy for Uncomplicated Bone Metastases on Pain, Function and Degree of Symptom Distress

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Purpose/Objective(s): To compare patient reported outcomes (PROs) following single fraction (SF) as compared with multiple fraction (MF) radiation therapy (RT) for uncomplicated bone metastases in a population-based cohort.

Materials/Methods: Six centres at our institution participated in the Prospective Outcomes and Support Initiative (POSI), to record PROs prior to and 3 weeks following RT for uncomplicated bone metastases. Patients treated between May and December 2013 who provided PROs before and after RT were identified. PROs were standardized and designed to assess patients' perception of pain, function and symptom distress using a non-dichotomous, ordinal, 5-point scale. Comparisons were made between patients who received SF versus MF RT. SFRT versus MFRT was at the discretion of the treating oncologist. A multivariate logistic regression analysis was performed.

Results: 284 patients completed both pre and post-RT assessments. The mean age at diagnosis was 64 years, 50% were male, and 59% received SFRT. The three most common primary sites were genitourinary (29%), lung (24%) and breast (20%). Spine (47%) was the most common site treated. There were no significant differences in changes in mean PRO scores for pain (1.17 vs. 1.02 point improvement; p=0.74), function (0.74 vs. 0.82 point improvement; p=0.61) or degree of symptom distress (1.22 vs. 1.21 point improvement; p=0.94) between patients who received SFRT versus MFRT. Likewise, the proportion of patients with at least a 1-point improvement in pain (68.2% vs. 70.0%; p=0.78), function (73.2% vs. 66.7%; p=0.41), and distress (78.5% vs. 80.7%; p=0.74) were similar between SFRT and MFRT. After controlling for age at diagnosis, gender, fractionation, site of delivery, and disease site there was no significant difference in probability of having an improvement in at least one category between SFRT and MFRT (Odds Ratio=1.43; 95% CI 0.76-2.68; p=0.27).

Conclusions: Improvements in patients' pain, function and degree of distress were similar whether treated with SFRT or MFRT. These population-based data support the generalizability of the randomized controlled trials to real-world practice and confirm that SFRT should be the standard management policy for patients with uncomplicated bone metastases.

Author Disclosure Block: **J. Conway:** None. **I. Olivotto:** None. **S. Miller:** None. **R. Halperin:** None. **D. Hoegler:** None. **W. Beckham:** None. **J. Stephen:** None. **H. Daudt:** None. **J. French:** None. **R. Olson:** None.