CyberKnife® System Provides Long-term Disease Control for Prostate Cancer Patients

Prospective, Multi-institutional Study Shows CyberKnife SBRT Treatment Results in Low PSA Nadir for Low- and Intermediate-risk Prostate Cancer Patients

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: ARAY) announced today data from a prospective, Phase II, 17-center study which showed that treatment with the CyberKnife® System for low- and intermediate-risk prostate cancer provides excellent long-term results. At five years, the disease-free survival rate for low-risk prostate cancer patients was 100 percent and for intermediate-risk patients was 88.5 percent. These results were maintained by patients followed for seven years. The study was presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) in Orlando, Florida, February 16 – 18, 2017.

A low prostate specific antigen (PSA) value is associated with a reduced risk of cancer recurrence or metastases. The lower the PSA value and the longer it continues to decline the greater the patient's likelihood of achieving long-term disease free survival[1]. According to the study, the five-year median PSA was 0.1 ng/mL for low- and intermediate-risk prostate cancer patients receiving stereotactic body radiation therapy (SBRT) administered with the CyberKnife System. The median PSA value subsequently decreased to 0.035 ng/mL at the seven-year mark for patients followed to this time point.

Comparison to Other Prostate Cancer Studies
All patients participating in the study were treated with the CyberKnife System. The study is unmatched in that:

- A highly effective pattern of radiation could be delivered easily by any CyberKnife user as a routine part of their practice -- such plans require steep dose fall-off from high-dose regions to rectum, and would be difficult to deliver safely without continual image-guidance and automatic correction of beam aim;
- Treatment resulted in among the lowest PSA levels reached after radiation therapy (PSA nadirs); and
- The entire treatment was completed in four days.

The CyberKnife System was designed to deliver SBRT, a treatment process enabling the delivery of radiation throughout the body with an extremely high degree of precision. The system's unique ability to continually track and automatically correct for movement of the prostate in real-time throughout the entire treatment session provides distinct advantages when treating a tumor which can move as much as 10 mm in as little as 30 seconds[2].

"Outcomes from this long-term, prospective study reinforce that CyberKnife prostate SBRT is highly effective, with typically minimal side effects and impact on quality of life during and after treatment," said Donald B. Fuller, MD, at Genesis Healthcare Partners in San Diego, California and lead investigator of the study. "It is

important to note that nearly 90 percent of patients in the study were treated at community facilities across the United States, which may provide reassurance for men with localized prostate cancer that the results are achievable in their community setting."

Additional Study Outcomes

The study, "Five-Year Outcomes from a Prospective Multi-Institutional Trial of Heterogeneous Dosing Stereotactic Body Radiotherapy (SBRT) for Low- and Intermediate-Risk Prostate Cancer," evaluated a dosing regimen which emulated a high-dose brachytherapy (HDR) plan. It demonstrated that:

- Patients experienced low toxicity rates despite the high SBRT dosage and heterogeneous dose distribution specific to this study, with higher dosage in the prostate peripheral zone;
- The 5-year local and distant failure-free remission rates (98.3 percent and 97.3 percent, respectively), for the entire patient population, were achieved with the CyberKnife System alone. This enables patients to avoid the unfortunate side effects associated with the use of androgen deprivation therapy (aka "hormone therapy") including loss of libido, hot flashes, bone fractures and weight gain[3]; and
- The results were obtained without the need for invasive rectal balloons or spacers to spare the rectal wall.

"This is the second large, prospective, multi-institutional study to bring clinical evidence of the benefits of CyberKnife SBRT for the treatment of patients with low- to intermediate-risk prostate cancer. No other radiation therapy device for prostate SBRT is supported by such a robust clinical database," said Fabienne Hirigoyenberry-Lanson, PhD, vice president global clinical development, at Accuray. "These data show why CyberKnife prostate SBRT is increasingly being viewed as the treatment of choice by clinicians and patients who want a non-invasive option that provides excellent disease control with minimal side effects."

Details of a previously presented multi-institutional study titled, "Prospective Evaluation of CyberKnife Stereotactic Radiosurgery for Low- and Intermediate-Risk Prostate Cancer: Homogenous Dose Distribution," which showed that five treatments with the CyberKnife System provided excellent disease control for prostate cancer patients, can be found at http://www.accuray.com/pressroom/press-releases/prospective-multi-institutional-study-shows-five-treatments-cyberknife. The study was presented at the American Society for Radiation Oncology (ASTRO) 58th Annual Meeting and the 2016 Best of ASTRO meeting.

About the Heterogeneous Dosing SBRT Study

Seventeen institutions analyzed 259 prostate cancer patients; 112 low-risk and 147 intermediate-risk. Patients received an HDR-like heterogeneous dosing regimen of 38 Gy/four fractions delivered by the CyberKnife System. The primary study objectives were to determine biochemical disease free survival (bDFS) and measure the rates of acute and late genitourinary and gastrointestinal toxicities following treatment, and to compare the CyberKnife System bDFS rates to published HDR brachytherapy bDFS rates reported in the literature.

Important Safety Information

For Important Safety Information please refer to http://www.accuray.com/safety-statement-radiation-treatment

About Accuray

Accuray Incorporated (NASDAQ: ARAY) is a radiation oncology company that develops, manufactures and sells precise, innovative tumor treatment solutions that set the standard of care with the aim of helping patients live longer, better lives. The company's leading-edge technologies deliver the full range of radiation therapy and radiosurgery treatments. For more information, please visit www.accuray.com.

Safe Harbor Statement

Statements made in this press release that are not statements of historical fact are forward-looking statements and are subject to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release relate, but are not limited, to clinical applications, clinical results, patient outcomes, adoption of Accuray's technologies and Accuray's leadership position in radiation oncology innovation and technologies.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from expectations, including but not limited to the risks detailed from time to time under the heading "Risk Factors" in the company's report on Form 10-K, filed on August 24, 2016, the company's reports on Form 10-Q, filed on November 1, 2016 and February 3, 2017, and as updated periodically with the company's other filings with the SEC.

Forward-looking statements speak only as of the date the statements are made and are based on information available to Accuray at the time those statements are made and/or management's good faith belief as of that time with respect to future events. The company assumes no obligation to update forward-looking statements to reflect actual performance or results, changes in assumptions or changes in other factors affecting forward-looking information, except to the extent required by applicable securities laws. Accordingly, investors should not put undue reliance on any forward-looking statements.