ViewRay Announces Results of the First Prospective Clinical Trial on MR-guided Radiation Treatment for Prostate Cancer Without Implanted Markers

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Study Shows Low Incidence of Early Toxicity Using Stereotactic Body Radiation Therapy (SBRT) While Eliminating Potential Complications and Costs Associated with Implanted Markers

CLEVELAND, Aug. 19, 2019 /PRNewswire/ -- ViewRay, Inc. (Nasdaq: VRAY) announced today the acceptance of publication by the International Journal of Radiation Oncology, Biology and Physics of the first prospective clinical trial of MR-guided radiation therapy (MRgRT) in patients with localized prostate cancer. This robust study of clinician and patient reported outcomes demonstrated zero CTCAE v4 grade 3 or higher gastrointestinal (GI) and genitourinary (GU) toxicity and even lower incidence of grade 2 toxicity than investigators hypothesized. It is also one of the first prospective clinical trials to study SBRT in a mix of intermediate- and high-risk prostate cancer patients, a challenging patient population to treat. The journal is the official scientific journal of the American Society for Radiation Oncology.

Researchers from Amsterdam University Medical Centers enrolled 101 patients with intermediate- or high-risk prostate cancer in a prospective phase II clinical trial. All patients received MRgRT in five fractions of 7.25 Gy to the target volume using on-table adaptive techniques. The trial did not use implanted markers or tissue spacers because treatments were delivered under MR-guidance, thereby eliminating an invasive procedure, potentially associated complications, and implantation costs.

Results at three months showed that no early CTCAE v4.0 grade 3 GU or GI toxicity was observed, and the maximum cumulative grade 2 early GU and GI toxicity measured by any symptom at any study time point was 23.8% (study hypothesis 40%) and 5.0% (study hypothesis 15%). These results were obtained in a complex clinical cohort (59.4% high-risk patients) and are comparable to what would be typically observed in lower-risk populations, pointing to the potential benefits of MR-guided SBRT in this higher risk group. Additionally, the low incidence of early GI toxicity, despite the inclusion of the base of the seminal vesicles in 96 percent of patients, illustrates the benefit of MR-guidance and on-table adaptive re-planning. This technology facilitates smaller treatment margins while minimizing damage to surrounding tissue and critical structures, such as urethra, rectum, and bladder. The publication noted that incontinence was uncommon, reported by 4% of patients at the end of MRgRT and decreasing over time.

"SBRT offers significant promise in the treatment of prostate cancer. Our clinical trial takes that a step further in showcasing its value in patients with intermediate- and high-risk disease, with a focus on evaluating associated toxicities and quality of life outcomes," said principal investigator Anna Bruynzeel, M.D., Ph.D., Radiation Oncologist at Amsterdam UMC. "We see a lower incidence of GI and GU toxicity with MR-guidance as compared to similar SBRT prostate cancer studies. The results reinforce the value of MRIdian's real-time on-table adaptive treatment with automatic beam gating for prostate patients."

"This promising data in the treatment of prostate cancer with SBRT, enabled by the unique combination of MRIdian's ability to see, shape, and strike, is notable for patients and physicians," said Scott Drake, President and CEO. "MRIdian is providing physicians the confidence and tools they need to deliver ablative radiation doses both precisely and accurately while sparing sensitive structures near the target, in order to achieve better patient outcomes. We are pleased to add this prospective trial to our clinical data compendium and thank the team at Amsterdam UMC for their work to improve the lives of cancer patients."

The article in press can be viewed at https://www.redjournal.org/article/S0360-3016(19)33640-5/fulltext.

About the Study
Article in Press in the International Journal of Radiation Oncology, titled: "A prospective single-arm phase II study of stereotactic magnetic-resonance-guided adaptive radiotherapy for prostate cancer: Early toxicity results", authored by Anna M.E. Bruynzeel, MD, PhD, Shyama U. Tetar, MD, Swie S. Oei, MD, Suresh Senan, MRCP, FRCR, PhD, Cornelis J.A. Haasbeek, MD, PhD, Femke O.B. Spoelstra, MD, PhD, Anna H.M. Piet, MD, Philip Meijnen, MD, PhD, Marjolein A.B. Bakker van der Jagt, MD, Tamara Fraikin, Berend J. Slotman, MD, PhD, Reindert J.A. van Moorselaar, MD PhD, and Frank J. Lagerwaard, MD, PhD. According to the study, "The maximum cumulative grade ≥2 early GU and GI toxicity measured by any symptom at any study time point was 23.8% and 5.0%, respectively. No early grade 3 GI toxicity was observed. Early grade 3 GU toxicity was 0% and 5.9% according to the CTCAE and RTOG and scoring systems, respectively, as a result of different grading of radiation-cystitis. The low incidence of early GI toxicity was confirmed by patient-reported outcome data. GU grade ≥2 toxicity peaked to 19.8% at the end of MRgRT, followed by a return to the baseline average score at three months follow-up."

About ViewRay®
ViewRay, Inc. (Nasdaq: VRAY), designs, manufactures, and markets the MRIdian® radiation therapy system. MRIdian is built upon a proprietary high-definition MR imaging system designed from the ground up to address the unique challenges and clinical workflow for advanced radiation oncology. Unlike MR systems used in diagnostic radiology, MRIdian's high-definition MR was purpose-built to address specific challenges, including

beam distortion, skin toxicity, and other concerns that potentially may arise when high magnetic fields interact with radiation beams. ViewRay and MRIdian are registered trademarks of ViewRay, Inc.

Intended Use
The MRIdian Linac System, with magnetic resonance imaging capabilities, is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

About Amsterdam University Medical Center
Amsterdam UMC employs more than 15,000 professionals, treating over 350,000 patients a year at both its sites – AMC and VUmc. Working towards a future in which illnesses are prevented and the best treatment made available to all patients, Amsterdam UMC has developed new methods for diagnostics and treatment together with professionals from other renowned national and international institutions. The institute's main focus is on complex patient care and highly-specialized treatment of rare medical conditions. Amsterdam UMC teaches and trains thousands of young people to become doctors, specialists or nurses. Its researchers are clustered in eight research centers so that the institute can achieve its ambition of executing international, cutting-edge research. At Amsterdam UMC, AMC and VUmc are working together on academic patient care, scientific research and teaching and training.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Private Securities Litigation Reform Act. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the rate of new orders, upgrades and installations, ViewRay's financial guidance for the full year 2019 and ViewRay's conference call to discuss its first quarter results. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the ability to commercialize MRIdian Linac System, demand for ViewRay's products, the ability to convert backlog into revenue, and the timing of delivery of ViewRay's products, the timing, results and other uncertainties associated with clinical trials, the ability to raise the additional funding needed to continue to pursue ViewRay's business and product development plans, the inherent uncertainties associated with developing new products or technologies, competition in the industry in which ViewRay operates and overall market conditions. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to ViewRay's business in general, see ViewRay's current and future reports filed with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and its Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2019 and June 30, 2019, as updated periodically by the company's other filings with the SEC. These forward-looking statements are made as of the date of this press release, and ViewRay assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law.

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