MIRAGE Phase III Randomized Controlled Trial Demonstrates Superiority of MRIdian® MRI-Guidance in Stereotactic Body Radiotherapy (SBRT) for Localized Prostate Cancer

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Final outcomes comparing acute grade ≥2 genitourinary toxicity following MRI- vs. CT-guided prostate SBRT presented at ASTRO 2022

DENVER, Oct. 27, 2022 /PRNewswire/ -- ViewRay, Inc. (NASDAQ: VRAY) announced today that the final primary endpoint results from the phase III randomized single-center MIRAGE trial were presented at the 64th Annual Meeting of the American Society for Radiation Oncology (ASTRO) being held October 23-26, 2022, at the Henry B. Gonzalez Convention Center in San Antonio, Texas. The trial was independently conducted by investigators at UCLA and compared MRIdian MRI-guided SBRT vs. CT-guided SBRT for localized prostate cancer.

Final outcomes of the phase III randomized trial comparing acute grade ≥2 genitourinary (GU) toxicity following MRIdian MRI-guided vs. CT-guided prostate SBRT determined that MRI-guidance significantly reduced acute grade ≥2 GU and gastrointestinal (GI) toxicity. In the trial, 156 patients were randomized and received MRIdian MRI-guided SBRT or CT-guided SBRT (40 Gy in five fractions). Acute grade ≥2 GU toxicity rates were significantly lower with MRI-guidance vs. CT-guidance (24.4% in the MRI group vs. 43.4% in the CT group). Rates of acute grade ≥2 GI toxicity were also significantly lower with MRI-guidance (0.0% in the MRI group vs. 10.5% in the CT group). On multivariable analysis, which controls for differences in the use of hydrogel spacer, prostate size, and baseline urinary symptoms, the MRI-guidance arm was associated with a 60% reduction in odds of grade ≥2 GU toxicity.

Perhaps even more notably, there were improvements in multiple patient-reported outcomes. Significantly more patients receiving CT-guided SBRT experienced large increases in urinary symptoms, as measured by a >15 points increase in International Prostate Symptom Score (IPSS) (6.8% in the MRI group vs. 19.4% in the CT group). Similarly, a significantly greater percentage of patients experienced a clinically notable decrease in bowel-related quality of life with CT-guided, as measured by the Expanded Prostate Cancer Index Composite-26 (EPIC-26) survey (25.0% in the MRI group vs. 50.0% in the CT group). Finally, though it is too early to draw final conclusions as more than 2/3rds of men on the trial received hormonal therapy, exploratory analysis in men who did not receive hormonal therapy showed that patient-reported, sexual-function scores (by EPIC-26) decreased more in men receiving CT-guided SBRT.

"A major consideration with prostate SBRT is the margin of normal tissue around the target that is exposed to high-dose radiation. The highly positive final results of our phase III MIRAGE trial show that when MRI-guidance is used to shrink this margin, there are significant improvements in both physician-scored and patient-reported toxicity in terms of urinary and bowel side effects," said Amar Kishan, MD., Associate Professor and Chief of the Genitourinary Oncology Service at UCLA. "UCLA has had a robust, leading SBRT program since 2010, and we have long offered this to our patients using a CT-guided platform. With the positive results of our trial, we have shifted to almost exclusively offering MRI-guided SBRT. Though differences in late toxicity will take years to manifest, in the interim, these data provide strong support for the use of this advanced technology to treat with unprecedented tight margins."

The MRIdian system provides oncologists outstanding anatomical visualization through diagnostic-quality MR images and the ability to adapt a radiation therapy plan to the targeted cancer with the patient on the table. This combination allows physicians to define tight treatment margins to avoid unnecessary radiation exposure of vulnerable organs-at-risk and healthy tissue and allows the delivery of ablative radiation doses in five or fewer treatment sessions, without relying on implanted markers. By providing real-time continuous tracking of the target and organs-at-risk, MRIdian enables automatic gating of the radiation beam if the target moves outside the user-defined margins. This allows for delivery of the prescribed dose to the target, while sparing surrounding healthy tissue and critical structures, which results in minimizing toxicities typically associated with conventional radiation therapy.

To date, nearly 27,000 patients have been treated with MRIdian. Currently, 54 MRIdian systems are installed at hospitals around the world where they are used to treat a wide variety of solid tumors and are the focus of numerous ongoing research efforts. MRIdian has been the subject of hundreds of peer-reviewed publications, scientific meeting abstracts, and presentations. For a list of treatment centers, please visit: https://viewray.com/find-mridian-mri-guided-radiation-therapy/

Conflicts of Interest: Amar Kishan, M.D. discloses research funding from the Department of Defense, the National Institutes of Health, the Jonsson Comprehensive Cancer Foundation, the Prostate Cancer Foundation, and the American Society for Radiation Oncology. He also discloses research support, not related to this study, from ViewRay, Inc. He discloses consulting fees from ViewRay, Inc. and Varian Medical Systems, Inc. Dr. Kishan also discloses low-value stock held in ViewRay Inc.

Disclaimer: Nothing in this material is intended to provide specific medical advice or to take the place of written law or regulations.

Safety Statement
The MRIdian Linac System is not appropriate for all patients, including those who are not candidates for magnetic resonance imaging. Radiation treatments may cause side effects that can vary depending on the part of the body being treated. The most frequent ones are typically temporary and may include, but are not limited to, irritation to the respiratory, digestive, urinary, or reproductive systems; fatigue; nausea; skin irritation; and hair loss. In some patients, side effects can be severe. Treatment sessions may vary in complexity and duration. Radiation treatment is not appropriate for all cancers. You should discuss the potential for side effects and their severity as well as the benefits of radiation and magnetic resonance imaging with your doctor to make sure radiation treatment is right for you.

About ViewRay

ViewRay, Inc. (Nasdaq: VRAY), designs, manufactures, and markets the MRIdian® MRI-Guided 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.

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, ViewRay's financial guidance for the full year 2022, anticipated future orders, anticipated future operating and financial performance, treatment results, therapy adoption, innovation, and the performance of the MRIdian systems. 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 the MRIdian Linac System, demand for ViewRay's products, the ability to convert backlog into revenue, the timing of delivery of ViewRay's products, the timing, length, and severity of the COVID-19 pandemic, including its impacts across our businesses on demand, our operations and global supply chains, the 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, 2021 and its Quarterly Reports on Form 10-Q, as updated periodically with 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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