



## Findings Published in JAMA Oncology Demonstrate Superiority of MRIdian® MRI-Guidance in Stereotactic Body Radiotherapy (SBRT) for Localized Prostate Cancer

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*MIRAGE phase III randomized controlled trial shows a significant reduction in GU and GI toxicities with MRIdian® MRI-guided versus CT-guided SBRT*

DENVER, Jan. 12, 2023 /PRNewswire/ -- ViewRay, Inc. (NASDAQ: VRAY) today announced that findings from the phase III randomized controlled MIRAGE trial (NCT04384770) were published on January 12 in [JAMA Oncology](#). The MIRAGE trial compared MRI-guided and CT-guided stereotactic body radiation therapy (SBRT) for localized prostate cancer and found MRI-guided radiation therapy – delivered with MRIdian – to be superior in substantially reducing acute genitourinary (GU) and gastrointestinal (GI) toxicity. MRI-guided radiation was also associated with significantly better patient-reported quality of life metrics.

The MIRAGE trial was led by Amar Kishan, M.D. (first author) and Michael L. Steinberg, M.D. (senior author) at the University of California, Los Angeles (UCLA). The study was independently designed, conducted, and analyzed exclusively by UCLA. In this trial, the investigator team randomized 156 patients to receive either MRI-guided SBRT or CT-guided SBRT. Acute grade  $\geq 2$  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). Acute grade  $\geq 2$  GI toxicity rates were also significantly lower with MRI guidance (0.0% in the MRI group vs. 10.5% in the CT group). On multivariate analysis, which controls for differences in the use of a rectal spacer, prostate size, and baseline urinary symptoms, the MRI-guided arm was associated with a 60% reduction in odds of grade  $\geq 2$  GU toxicity.

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 conclude, 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.

"To our knowledge, this trial is the first phase III randomized controlled trial comparing MRI guidance to CT guidance in any disease site," said Dr. Steinberg, Professor and the Chair of the Department of Radiation Oncology at UCLA. "MRI-guided radiation has apparent theoretical benefits in this treatment scenario, and it was important to conduct a rigorous comparison. Given the significance of the outcomes realized, we've evolved our prostate cancer treatment approach at UCLA to preferentially utilize MRI-guided SBRT."

"Radiation is accepted as an effective and safe standard-of-care option for many men with prostate cancer, but there is always the opportunity for improvement of reducing toxicity. The prostate is a highly mobile target, and the motion of the prostate needs to be accounted for to maximize treatment effectiveness. Accounting for this motion typically requires creating a margin around the prostate (rather than just the prostate itself)," said Dr. Kishan, Associate Professor and Chief of the Genitourinary Oncology Service at UCLA. "We felt that MRI-guided radiotherapy allows a much tighter margin around the prostate to be targeted due to both the enhanced imaging capabilities of MRI and the ability to track the prostate and control the beam in real time during treatment. The significant reduction in urinary and bowel toxicity seen in our trial reflects the importance and relevance of this tighter margin made possible by MRI-guided radiation therapy."

To date, more than 27,000 patients have been treated with MRIdian. Currently, 56 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.

**Conflicts of Interest:** Michael L. Steinberg, M.D. discloses health policy consulting fees from ViewRay, Inc.

### **Disclaimer:**

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

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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