# Interim Findings from MIRAGE Phase III Randomized Trial Signal Superiority of MRIdian® MRI-guidance in Stereotactic Body Radiotherapy (SBRT) for Localized Prostate Cancer

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**Poster on Interim Trial Data Comparing MRI-Guided vs. CT-Guided SBRT Toxicities for Prostate Cancer to be Featured at American Society of Clinical Oncology GU Cancers Symposium**

CLEVELAND, Feb. 15, 2022 /PRNewswire/ -- ViewRay, Inc. (NASDAQ: VRAY) today announced that interim data from the single center Phase III randomized MIRAGE trial, led by UCLA, comparing MRIdian MRI-guided vs. CT-guided SBRT for localized prostate cancer, will be featured at the 2022 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium, held February 17-19 in San Francisco. Interim analysis of the primary endpoint signaled superiority of MRIdian MRI-guided SBRT with a significant reduction in acute grade ≥2 GU toxicity in men receiving MRI-guided SBRT over those receiving CT-guided SBRT.

The poster, titled "Magnetic resonance imaging-guided versus computed tomography-guided stereotactic body radiotherapy for prostate cancer (MIRAGE): Interim analysis of a phase III randomized trial" and authored by Amar Kishan, MD., Associate Professor and Chief of the Genitourinary Oncology Service at UCLA, will be showcased on Thursday, February 17 from 11:30 AM PT to 1:00 PM PT as part of the Prostate Cancer poster session. Following the poster session, Dr. Kishan (@AmarUKishan) will host a LIVE Twitter Q&A to answer questions about the interim findings. Those interested can join the conversation and post their questions using #MIRAGEQA.

The interim analysis of data from 100 patients eligible for evaluation (51 in the CT group and 49 in the MRI group) showed a statistically significant reduction in acute grade ≥2 GU toxicity in men receiving MRI-guided SBRT (47.1 percent in the CT group vs. 22.4 percent in the MRI group) and a significant reduction in acute grade ≥2 gastrointestinal (GI) toxicity in men receiving MRI-guided SBRT (13.7 percent in the CT group vs. 0 percent in the MRI group). Acute grade ≥2 GU toxicity can include adverse events range from frequent, urgent, or painful urination to pelvis pain, bladder spasms, or blood in the urine. Acute grade ≥2 GI toxicity can include adverse events ranging from diarrhea, discharge, or rectal/abdominal pain to abdominal distention or obstruction.

Patient-reported outcomes were measured using the International Prostate Symptom Score (I-PSS) and Expanded Prostate cancer Index Composite (EPIC-26). Patient reported urinary and bowel function metrics were better preserved at the 1-month time point with MRI-guidance, though this difference dissipates at the 3-month time point, potentially due to management of side effects.

"Beyond a reduction in the standardized metric of physician-scored toxicity, we also saw differences in one-month patient-reported urinary and bowel function metrics favoring the MRI-guidance arm. These data are highly indicative of less radiation dose being delivered to sensitive structures, such as the bladder, urethra, and rectum, with MRI-guidance," said Dr. Kishan. "Potential explanations for the magnitude of these results can be attributed to the real-time tissue tracking of actual anatomy and automatic gating of beam delivery, which thereby allows for tighter contours and treatment of smaller volumes. The high dose regions are significantly smaller for patients receiving MRI-guided SBRT."

Given the large primary endpoint signal seen, the study protocol was amended to reduce the projected sample size from 300 to 154, requiring half the number of patients while still maintaining 89 percent power to demonstrate superiority. Accrual of the MIRAGE trial (NCT04384770) was completed as of October 2021 and a final analysis for the primary endpoint is anticipated in early 2022.

"While the final results are still being analyzed, it is evident from our interim analysis that the benefit provided by MRI-guidance over CT-guidance for the delivery of SBRT for localized prostate cancer is projected to be large enough that we were able to cut the projected size of our trial in half. In fact, by the time this interim analysis was done, we had already enrolled enough patients to close the trial successfully," said Dr. Kishan. "In anticipation of the highly positive result implied by this interim analysis, we have now shifted to routinely offering MRI-guided SBRT at UCLA."

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.

Nearly 18,000 patients have been treated with MRIdian. Currently, 48 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/

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The opinions and clinical experiences discussed herein are specific to the featured physicians and are for information purposes only. Nothing in this material is intended to provide specific medical advice or to take the place of written law or regulations. Results of treatment presented in this press release are not indicative of typical or future results.

**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.

**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. AUK discloses consulting fees from ViewRay, Inc. and Varian Medical Systems, Inc. Dr. Kishan also discloses low-value stock held in ViewRay Inc.

**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, anticipated future orders, ViewRay's financial guidance for the full year 2021, 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 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 recent COVID-19 (coronavirus) pandemic, including its impacts across our businesses on demand, operations and our 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, 2020 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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