First Toxicity Results from SCIMITAR Prospective Phase II Trial Signal Favorable Toxicity Profile of Post-Prostatectomy Stereotactic Body Radiotherapy (SBRT) for Prostate Cancer

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Post-hoc Analysis Highlights Reduction in Gastrointestinal (GI) Toxicity with MRIdian® MRI-guided SBRT Compared to CT-guided SBRT, with No MRI-guided SBRT Patients Experiencing Grade 3 Genitourinary (GU) or Grade ≥2 Gastrointestinal Toxicity

CLEVELAND, March 10, 2022 /PRNewswire/ -- ViewRay, Inc. (NASDAQ: VRAY) today announced the first toxicity results from the prospective single-arm Phase II SCIMITAR trial. A secondary analysis compared the findings of treatment under CT-guidance to MRI-guidance and found that patients treated with MRI-guidance had a 30.5 percent reduction in any grade acute GI toxicity and a 32 percent reduction in any grade cumulative GI toxicity up to 6 months. No patient treated with MRI-guided radiation therapy experienced any grade 3 GU or GI toxicity. Initial toxicity results are being presented by UCLA Department of Radiation Oncology resident, T. Martin Ma, M.D., Ph.D., at The Radiation Oncology Summit: ACRO 2022, held March 9-12, 2022, in Fort Lauderdale, Florida.

Surgery, known as prostatectomy, is a common treatment for prostate cancer and it is estimated that up to 1/3 of patients will experience some recurrence of their cancer within 10 years after their prostatectomy. The current standard treatment for most patients with recurrent prostate cancer after surgery is up to 7-8 weeks of radiation therapy.

UCLA is at the forefront of studying SBRT for intact prostate, recently announcing interim data from their single center Phase III randomized MIRAGE trial (NCT04384770), which signaled superiority of MRI-guided SBRT over CT-guided SBRT for localized prostate cancer. Five fraction SBRT in the post-prostatectomy setting is currently only possible within a clinical trial, and the prospective Phase II "StereotaCtic Intensity Modulated RadIoTherapy After Radical Prostatectomy" (SCIMITAR) trial led by UCLA is examining the safety and efficacy of postoperative SBRT at a dose of 30-34 Gy in five fractions (NCT03541850).

The first toxicity results from the trial, which will be presented at ACRO 2022, evaluated 100 patients with recurrent prostate cancer after radical prostatectomy. The patients underwent SBRT delivered under either CT guidance or MRI guidance. Acute and late genitourinary (GU) and gastrointestinal (GI) toxicity were evaluated based on the Common Terminology Criteria for Adverse Events (CTCAE version 4.03). Patient-reported toxicity outcomes (PRO) were based on Expanded Prostate Cancer Index-26 (EPIC-26) instrument and International Prostate Symptom Scores (IPSS).

SBRT after prostatectomy was feasible, with a favorable overall toxicity profile both in clinician-scored and patient-reported outcome measurements. However, the post-hoc analysis signaled that MRI-guided radiation therapy may be associated with reduced acute physician-scored GI toxicity.

"When treating patients after a radical prostatectomy, the radiation target volume is a broader area between the rectum and the bladder. Because the rectum and the bladder can change shape and move, both between treatments and during treatments, we have had to use fairly generous "safety margins" when designing our radiation. That means we need to provide a dose to an area broader than just the target volume to ensure that we don't miss. For instance, on a recent nationwide trial, these margins ranged from 7 mm to 1 cm," said Amar Kishan, M.D., Associate Professor and Vice Chair of Clinical and Translational Research at UCLA. "In this current study, we used advanced technology to reduce this margin to 5 mm for patients receiving CT-guided treatment. However, MRI-guidance offers additional advantages: not only a clearer picture when treating, but the ability to "track" motion in real-time. Specifically, we tracked the wall of the rectum using an MRI obtained four times per second. Due to this, we reduced our margins even further, to 3 mm. We have shown this does not reduce the ability to cover the target area, and this significant reduction in margins likely explains the toxicity benefit we observed. In fact, this is analogous to a significant difference in GI toxicity, favoring MRI-guidance, that we saw in a trial directly comparing MRI and CT guided SBRT for patients receiving upfront radiation for their prostate cancer."

The SCIMITAR trial will assess 4-year biochemical recurrence-free survival and analysis of the primary endpoint is planned once the 100th patient has 2-year PRO data available.

Additionally, another Phase II trial called SHORTER (NCT044221320) is underway at NewYork-Presbyterian/Weill Cornell Medicine, comparing in a randomized manner urinary and bowel side effects of MRI-guided hypofractionated radiotherapy in 20 treatments (4 weeks) to MRI-guided ultra-hypofractionated radiotherapy in 5 treatments (2 weeks) for prostate cancer that has returned after prostatectomy.

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, 50 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 related to this study from ViewRay, Inc. Dr. Kishan 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, 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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