ViewRay Announces Primary Endpoint Outcome from First Prospective, Multi-Institutional Study to Deliver Ablative Doses of Radiation to Pancreatic Cancer Patients

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Study's primary objective of low grade 3+ toxicity was met; exploration of secondary outcomes underway to confirm local control rates and patient outcomes with MRIdian SMART

DENVER, Oct. 24, 2022 /PRNewswire/ -- ViewRay, Inc. (NASDAQ: VRAY) announced today that the findings from the first Phase II prospective international multi-institutional study to deliver ablative doses of radiation to pancreatic cancer patients will be 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. The results will be featured as part of the Special Session of Late-Breaking Abstracts and will take place on Tuesday, October 25, at 3:00 p.m. Central Time. The data will be presented by Parag Parikh, M.D., study's principal investigator and Director of GI Radiation Oncology and MR-Guided Radiation Therapy at the Henry Ford Cancer Institute in Detroit.

The trial, titled "Stereotactic MRI-Guided On-table Adaptive Radiation Therapy (SMART) for Locally Advanced Pancreatic Cancer" – and known as SMART Pancreas (NCT 03621644) – was launched in 2019 in response to compelling retrospective data that suggested the potential for ablative dose radiation to improve overall survival relative to patients receiving lower radiation doses without increasing the rate of severe gastrointestinal toxicity.

In the SMART Pancreas study, 136 patients were treated at 13 international centers with ablative MRIdian SMART, 50Gy over 5 fractions. The study's primary outcome measured grade 3 or higher gastrointestinal toxicity in the first 90 days after treatment. The study's primary safety objective was met, with zero incidences of acute grade 3+ GI toxicity definitely-related to SMART treatment.

Secondary measures of the study include overall survival, local control, distant progression-free survival, and changes in patient-reported quality of life. While study patients are still early in the follow-up period, 16.4 months from diagnosis and 8.8 months from SMART treatment, the ASTRO presentation will highlight preliminary clinical outcomes data of 1-year local control and distant progression-free survival were 82.9% and 50.6% respectively. One-year overall survival from diagnosis was 93.9%.

"We are pleased to see this prospective study confirmed our experience using MRIdian for pancreas cancer. Ablative SMART for locally advanced and borderline resectable pancreatic cancer is safe; and is promising to improve patient outcomes in this devastating disease," said Dr. Parikh. This study supports further studies looking at overall survival, such as the LAP-ABLATE randomized study that was recently opened."

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: Parag Parikh, M.D. discloses research funding and consulting from ViewRay, Inc, and research funding from Galera Therapeutics, Inc. He also discloses stock ownership from Nuvaira, 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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