ViewRay Announces 510(k) Pending Status of the Newest Generation of MRIdian Innovations

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New suite of workflow and clinical features to be highlighted at upcoming ASTRO 2021 conference

CLEVELAND, Sept. 29, 2021 /PRNewswire/ -- ViewRay, Inc. (NASDAQ: VRAY) today announced that the company has received acceptance from the FDA on their recent submission for new MRIdian features focused on enhancing on-table adaptive workflow efficiency and expanding clinical utility. ViewRay will be exhibiting at the annual ASTRO 2021 conference in Chicago, IL from October 24— October 26 and will be highlighting the new technological advancements during the conference.

ViewRay's 510(k) pending submission consists of features including new MRI imaging sequences, automated workflow steps, on-table auto-contouring tools, multi-planar tissue tracking and automated beam gating, and the ability for clinicians to work collaboratively during patient treatments. The submission also includes a new brain treatment package and the integration of a real-time patient feedback display.

"We are pleased to announce this significant milestone in our development roadmap. ViewRay continues to be the leading innovator of MR-guided radiation therapy by now offering a new suite of features including multi-planar tissue tracking which enhances our industry-unique automatic beam gating technology", says Scott Drake, ViewRay President and CEO, "As the number of MRIdian programs expands globally, customers have reinforced that they desire faster treatment times and expanding MRIdian treatments to additional disease sites. The technology submitted in our 510(k) is intended to address these customer requests."

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 nearby organs-at-risk 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 surrounding healthy tissues, 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.

More than 14,300 patients have been treated with MRIdian SMART (Stereotactic MR-guided Adaptive Radiotherapy). Currently, 45 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/

Disclaimer:
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.

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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