ViewRay Announces FDA 510(k) Clearance for Advancements in MRI and Functional Imaging Technologies for MRIdian MRI-Guided Radiation Therapy System

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Proprietary Technology from ViewRay Enables Imaging and Treatment Enhancements

CLEVELAND, Feb. 21, 2019 /PRNewswire/ -- ViewRay, Inc. (Nasdaq: VRAY), announced today that the company received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market new soft tissue visualization capabilities for its MRIdian system.

The new upgradable capabilities enhance the industry-leading features of MRIdian's SmartVISION MRI, including:

- Expanded high-definition visualization and enhanced contrast between different tissues, to assist clinicians with tissue visualization and beam contouring
- The potential to aid in the assessment and prediction of tumor response to radiation therapy is enabled by "DWI", our diffusion weighted imaging feature which tracks treatment progress by distinguishing between tumor and normal tissues
- Faster, brighter, more detailed anatomical planar imaging to strike tumors with greater precision and accuracy through our proprietary technology, which allows for a 2X increase in MR imaging speed (to 8 frames per second), a 2X increase in image resolution, and a 2X improvement in MR signal-to-noise ratio (SNR)
- Potential reduction in treatment delivery time through enhanced MLC speed

"Today we announce another significant step forward in our drive to better treat cancer patients and further differentiate MRIdian in the marketplace", said James Dempsey, Ph.D., Founder and Chief Scientific Officer of ViewRay. "Our customers are seeking significant improvements on imaging speed, resolution and brightness. They also demand that we avoid artifacts and distortions that have historically and consistently plagued the field. We believe these innovations hit the mark. We will continue to advance the field of MR Guided Radiation Therapy and expand the application of the MRIdian system."

MRIdian's SmartVISION provides high-definition, diagnostic-quality MR imaging. SmartVISION was designed to maintain high-fidelity beam delivery, while mitigating the risks of skin toxicities, as well as trapped or distorted dose. MRIdian's SmartADAPT helps allow clinicians to generate daily MR setup scans in seconds and leverage high-contrast anatomical detail to rapidly reshape dose delivery based on the current position of both the tumor and adjacent critical structures – all while the patient is in the treatment position. MRIdian's SmartTARGET visualizes the tumor's edges and surrounding organ position in real-time using a non-ionizing, streaming video perspective. When tumors or organs-at-risk change shape or position, SmartTARGET instantly reacts, automatically controlling beam delivery.

About ViewRay®
ViewRay, Inc. (Nasdaq: VRAY), designs, manufactures and markets the MRIdian® 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.

Intended Use: The MRIdian Linac System, with magnetic resonance imaging capabilities, is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Forward Looking Statements: This press release contains forward-looking statements. Statements in this press release that are not purely historical are forward-looking statements. These statements are subject to risks and uncertainties that could cause future results to differ materially from those referenced. Forward-looking statements include, but are not limited to, statements about ViewRay's financial results and market acceptance of ViewRay's existing products, future products or technology. Words such as "could," "anticipates," "expects," "outlook," "intends," "plans," "believes," "seeks," "vision," "estimates," "may," "will," "future," "horizon," "aiming," "driving," "target" (or variations of them) and similar statements, are forward-looking statements. Forward-looking statements involve risks, uncertainties and assumptions that are difficult to predict and could cause ViewRay's results to differ materially from those presented. These risks, uncertainties and assumptions include, but are not limited to, changes in: the regulatory environment; global economics; trade compliance requirements, duties or tariffs; third-party reimbursement levels; currency exchange rates; taxation, healthcare law, and product clearance requirements, as well as those related to: adverse publicity about ViewRay and our products; our reliance on sole or limited source suppliers; our ability to commercialize our products successfully; the impact of competitive products and pricing, and all other risks listed from time to time in the company's filings with the Securities and Exchange Commission, available at www.sec.gov, which are incorporated

into this Forward-Looking Statements disclosure by this reference. 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 differ from those projected in the forward-looking statements, except as required by law.

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Investor Contact: Michaella Gallina, Senior Director, Investor Relations and Communications, ViewRay, Inc., 1-844-MRIdian (674-3426), investors@viewray.com; Media Contact: Karen Hackstaff, Senior Director, Downstream Marketing, ViewRay, Inc.,1-844-MRIdian (674-3426), media@viewray.com