ViewRay Announces First Patient Enrolled in Stereotactic MRI-guided On-table Adaptive Radiation Therapy (SMART) Trial for Locally Advanced Pancreatic Cancer

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Study to Explore Clinical Benefits of Precise, High Dose Radiation Therapy Enabled by MRIdian's MR-guidance Combined with Daily On-table Adaptation in Pancreatic Cancer

CLEVELAND, Jan. 4, 2019 /PRNewswire/ -- ViewRay, Inc. (Nasdaq: VRAY) announced today the enrollment of the first patient in the Stereotactic MRI-guided On-table Adaptive Radiation Therapy (SMART) Trial, a multi-center, prospective clinical trial for locally advanced or borderline pancreatic cancer. The trial will explore the clinical benefits of precise, high dose radiation therapy enabled by MR-guidance combined with daily on-table adaptation in the treatment of pancreatic cancer.

Retrospective analysis of precise, high-dose MR-guided radiation therapy delivered using adaptive dose planning has shown promising results with locally advanced pancreatic cancer, suggesting the potential for improving overall survival relative to patients receiving lower radiation doses, without increasing the rate of serious gastrointestinal toxicity. The compelling nature of the retrospective data prompted the SMART trial, aimed at investigating in a controlled, prospective manner, the robustness of this outcome and tracking quality of life over a 5-year trial period.

"High-definition MR and daily treatment plan adaptation allow us to deliver ablative radiation doses safely to pancreatic cancer patients for the first time ever," said Parag Parikh, M.D., co-PI of the study and Director of GI Radiation Oncology and MR-Guided Radiation Therapy at the Henry Ford Cancer Institute in Detroit. "Through the SMART trial, we will build upon the promising experience from UCLA, Washington University, Amsterdam UMC, University of Miami and University of Wisconsin by further exploring MRIdian's impact on associated toxicity, local control and patient outcomes in pancreatic cancer at multiple institutions around the world."

The SMART trial is the first prospective, multi-institutional study to deliver ablative doses of radiation to pancreatic cancer patients. It aims to enroll 133 participants with borderline resectable or inoperable locally advanced pancreatic cancer. In the single-arm study, participants will receive radiation therapy at a dose of 50 Gray in 5 fractions (treatment sessions) using ViewRay's MRIdian. On-table adaptive re-planning will be used when clinically indicated. In all patients, real-time MRI imaging will be used throughout treatment delivery to monitor the target location and control the radiation beam as necessary.

The trial's primary outcome measure is grade 3 or higher gastrointestinal toxicity in the first 90 days after treatment, with secondary measures including overall survival at two years, distant progression-free survival at six months, and changes in patient-reported quality of life.

"Early evidence on the use of MRIdian to treat locally advanced pancreatic cancer suggests the potential for significantly prolonged survival and lower toxicity rates. Through this rigorously designed study, we hope to further validate the long-term benefits of treatment on the MRIdian," said Scott Drake, President and Chief Executive Officer of ViewRay. "We believe MRIdian's unique combination of real-time visualization, automated beam control, and daily on-table treatment adaptation has the potential to become the standard of care in radiation oncology."

Along with Parag Parikh, M.D. from Henry Ford Cancer Institute, the trial is led by Percy Lee, M.D. from the University of California Los Angeles.

For more information on the SMART trial, please visit https://clinicaltrials.gov/ct2/show/NCT03621644.

About the SMART Trial

The SMART trial is designed to enroll 133 participants with borderline resectable or inoperable locally advanced pancreatic cancer. Patients must be 18 years and older and have documented non-metastatic disease after 3 months of systemic therapy. Radiation therapy will be delivered using ViewRay's MRIdian at a prescribed dose of 50 Gray (Gy) in 5 fractions. Each participant will be aligned in the treatment system with MRI image-guidance. On-table adaptive re-planning will be used when clinically indicated. In all patients, real-time MRI imaging will be used throughout treatment delivery to monitor the target location and control the radiation beam as necessary. The primary outcome measure of the study is grade 3 or higher gastrointestinal toxicity in the first 90 days after treatment. Secondary measures include overall survival at two years, distant progression-free survival at six months and changes in patient reported quality of life (pre-treatment to 12 months post-treatment and for longer periods up to five years).

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 references to the recent study results, clinical trial results, related clinical experience and patient outcomes. Given these uncertainties, the reader is advised not to place any undue reliance on any forward-looking statements. Additional risk factors include, among others, 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, government and regulatory uncertainty, including but not limited to obtaining authorizations to market and new tariffs and trade restrictions, and overall market conditions. 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. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents ViewRay files with the SEC available at www.sec.gov.

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