Cleveland, April 11, 2019 - ViewRay, Inc. (Nasdaq: VRAY) announced today the publication of a retrospective analysis of outcomes for the stereotactic treatment of locally advanced pancreatic cancer using precise, high-dose MRI-guided radiation therapy delivered with MRIdian’s on-table adaptive dose planning system. The study, published in Cancer Medicine, and led by Soumon Rudra, M.D. from Washington University in St. Louis, demonstrated enhanced overall survival while resulting in lower levels of toxicity compared to lower-dose, mostly non-adaptive treatment. These outcomes inspired the ongoing SMART trial, a multi-institutional prospective trial intended to assess the outcomes of this retrospective analysis further.

Researchers at Washington University in St. Louis, the University of Wisconsin, the University of California Los Angeles, University of Miami, and Amsterdam University Medical Centers, pooled outcomes from 44 pancreatic cancer patients treated with the MRIdian system. About half of the patients were treated with high doses (greater than 70 Gy BED), often with on-table adaptive planning to improve normal tissue sparing and, in some instances, to increase the dose to the tumor. The other half of patients received lower doses (less than 70 Gy BED) and were less likely to have received on-table adaptive planning. The high-dose group showed overall survival at two years of 49 percent, versus 30 percent for the low-dose group. Importantly, no patient in the high-dose group experienced Grade 3 or higher acute toxicity, while 15 percent in the low-dose group experienced Grade 3 or 4 toxicity.

Pancreatic tumors and surrounding healthy organs and tissue can vary significantly in position and size from day to day. This variation can increase the risk of delivering therapeutic radiation that damages healthy tissues and organs. Daily MRI guidance enabled by MRIdian allows clinicians to assess the position of the target relative to sensitive organs and adjust the treatment plan at the moment of treatment in order to minimize radiation exposure to healthy tissues and allow for an increased dose to be delivered to the disease. The higher dose also provides for a shortened treatment course versus low dose therapy.

"The combination of on-table adaptive re-planning and real-time tracking and gating of tumor motion enables us to confidently deliver very high, potentially curative doses," said Percy Lee, Associate Professor and Vice Chair of Education, and Director of the Stereotactic Body Radiotherapy Program at the David Geffen School of Medicine at UCLA. "Locally advanced pancreatic cancer is notoriously difficult to treat, and the outcomes noted in this retrospective study are better than expected and very encouraging. The features of the MRIdian system have a demonstrated potential to improve treatments for patients with many types of cancer."

“These data suggest that MRIdian-guided adaptive radiotherapy may help survival while greatly reducing toxicity rates,” said Scott Drake, President and Chief Executive Officer of ViewRay. “We are pleased to support the prospective study of this promising finding and thank the multi-institutional teams for their work to improve patient care and outcomes."

About the Publication


According to the publication, “The study was a multi-institutional, retrospective, cohort study based on data from 5 institutions. Eligible patients had biopsy-proven, inoperable, pancreatic cancer treated with MRgRT from 2014 through 2016. All patients were evaluated with diagnostic computed tomography (CT) imaging or MRI. Patients deemed medically inoperable were included as well. The study excluded patients with prior pancreas-directed RT, pancreatic surgery or any clinical-radiographic evidence of distant metastasis prior to initiation of RT. Research conformed to the Helsinki Declaration and satisfied retrospective review requirements for each institution.”

The publication can be viewed at: https://onlinelibrary.wiley.com/doi/epdf/10.1002/cam4.2100.

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 three 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 more extended 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 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, the rate of new orders, upgrades and installations, ViewRay's financial guidance for the full year 2019 and ViewRay's conference call to discuss its fourth quarter and year to date results. 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, and the timing of delivery of ViewRay's products, the timing, 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, 2018, 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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