



## Miami Cancer Institute Enrolls First Patients in Single-Fraction Stereotactic MRI-Guided Adaptive Radiation Therapy for Inoperable Primary or Metastatic Cancer Trial

July 7, 2021

### Investigator-Led Study Explores Feasibility and Tolerability of Single-fraction Stereotactic Ablative Body Radiotherapy Using MRIdian's Daily MRI-Guidance with On-Table Adaptive Replanning

CLEVELAND, July 7, 2021 /PRNewswire/ -- ViewRay, Inc. (NASDAQ: VRAY) today announced that the Miami Cancer Institute, part of Baptist Health South Florida, has enrolled the first patients in its "Stereotactic MRI-guided Adaptive Radiation Therapy (SMART) in One Fraction for Inoperable Primary or Metastatic Carcinoma" clinical study – referred to as the SMART ONE trial (NCT#04939246). This single-arm prospective study that was developed and led by [Dr. Michael Chuong](#), MD, FACRO, radiation oncologist and Medical Director of Proton Therapy and MR-guided Therapy at Miami Cancer Institute, is exploring the feasibility and tolerability of single-fraction stereotactic ablative body radiation therapy (SABR) for primary or metastatic carcinoma involving the lung, liver, adrenal gland, abdominal/pelvic lymph node, pancreas, and kidney.\*

The use of MRI instead of CT for daily image guidance offers several important advantages in the delivery of SABR including superior visualization of the internal anatomy prior to and uniquely continuously during treatment delivery.

SABR is an advanced and technically complex procedure in which very high radiation dose is delivered using steep dose gradients with millimeter precision and accuracy. The most common delivery schedule is daily treatment for five total days to each targeted tumor. While completing treatment in only one day may be possible, it is not commonly done using CT-guided radiation delivery machines because of safety concerns due to limitations in visual confirmation of tumor and nearby critical organ position throughout treatment.

MRIdian's design allows clinicians the ability to safely deliver an ablative dose and expand single-fraction SABR to tumors that would not have been previously considered. The design includes diagnostic-quality anatomic imaging prior to treatment delivery, the ability to perform on-table adaptive planning and continuous intrafraction visualization, soft tissue tracking and automatic beam gating. These features facilitate tighter planning target volume margins to spare healthy tissue, especially in immediate proximity to the target, which allow for reduction or elimination of higher-grade toxicities often associated with SABR dose delivery.

"With MRIdian, we're giving clinicians the clinical confidence to safely deliver ablative radiation doses while also reducing the number of treatments," said Martin Fuss, M.D., chief medical officer at ViewRay. "MRI-guidance and on-table adaptive delivery ensure that these powerful radiation doses are reaching the target but avoid highly sensitive surrounding critical structures. We believe this treatment concept has the potential to alleviate toxicity risks associated with SABR while improving outcomes for cancer patients around the world."

A growing body of clinical literature has led to the initiation of the SMART ONE trial design. This evidence describes favorable outcomes of image-guided SABR for various cancers, including tumors in the pancreas, liver, lung, breast, adrenal gland, kidney, lymph nodes, and prostate; however, the peer-reviewed, published body of data has nearly exclusively been based on multi-fraction SABR.

"Published experience suggests that delivery of single-fraction SABR using MRIdian should be at least isotoxic and isoeffective as compared to multi-fraction SABR, as supported by its on-table adaptive planning capabilities and continuous soft-tissue tracking with automatic beam gating," said Dr. Chuong. "We believe the study will demonstrate the feasibility to safely and effectively deliver SABR in only one fraction across these indications that will not only shorten overall treatment time, but also reduce cost and improve increase patient convenience."

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 12,500 patients have been treated with MRIdian. Currently, 44 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/>

\*ViewRay has provided grant funding to Miami Cancer Institute in support of the SMART ONE trial. [Dr. Michael Chuong](#) has served on advisory boards of, and received honoraria from, ViewRay.

#### 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.

ViewRay is a medical device manufacturer and cannot and does not recommend specific treatment approaches. Individual results may vary. The results described herein may not be predictive.


### **About Miami Cancer Institute**

Miami Cancer Institute brings to South Florida access to personalized clinical treatments and comprehensive support services delivered with unparalleled compassion. No other cancer program in the region has the combination of cancer-fighting expertise and advanced technology—including the first proton therapy center in South Florida, Latin America and the Caribbean, and one of the only radiation oncology programs in the world with each of the newest radiation therapies in one place—to diagnose and deliver precise cancer treatments that achieve the best outcomes and improve the lives of cancer patients. The Institute offers an impressive roster of established community oncologists and renowned experts, clinical researchers and genomic scientists recruited from the nation's top cancer centers. Selected as Florida's only member of the Memorial Sloan Kettering Cancer (MSK) Alliance, Miami Cancer Institute is part of a meaningful clinical collaboration that affords patients in South Florida access to innovative treatments and ensures that the standards of care developed by their multidisciplinary disease management teams match those at MSK.

Miami Cancer Institute is part of Baptist Health South Florida, the largest healthcare organization in the region, with 11 hospitals, more than 23,000 employees, 4,000 physicians and 100 outpatient centers, urgent care facilities and physician practices spanning across Miami-Dade, Monroe, Broward and Palm Beach counties. Baptist Health has internationally renowned centers of excellence in cancer, cardiovascular care, orthopedics and sports medicine, and neurosciences. In addition, it includes Baptist Health Medical Group; Baptist Health Quality Network; and Baptist Health Care On Demand, a virtual health platform. A not-for-profit organization supported by philanthropy and committed to its faith-based charitable mission of medical excellence, Baptist Health has been recognized by Fortune as one of the 100 Best Companies to Work For in America and by Ethisphere as one of the World's Most Ethical Companies. For more information, visit [BaptistHealth.net/Newsroom](https://www.baptisthealth.net/newsroom) and connect with us on Facebook, Instagram, Twitter and LinkedIn: @BaptistHealthSF | FB: [@Miami Cancer Institute](https://www.facebook.com/MiamiCancerInstitute) | TW: @miamicancerinst | IG: @miamicancerinstitute

### **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 and ViewRay's anticipated future operating and financial performance, treatment results 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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