



## **ViewRay Announces 1-Year Outcomes on MR-Guided Radiation Treatment for Prostate Cancer Without Implanted Markers**

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### **Study Shows Low Incidence of Toxicity Using Stereotactic Body Radiation Therapy (SBRT) While Reducing Potential Complications Associated with Implanted Markers**

CLEVELAND, June 23, 2020 /PRNewswire/ -- ViewRay, Inc. (Nasdaq: VRAY) announced today the publication by the European Urology Oncology Journal of a prospective phase II study of MR-guided radiation therapy (MRgRT) in patients with localized prostate cancer. The publication is a follow-up to early outcomes published in 2019 which reported low incidence of acute toxicity in both clinician- and patient-reported outcomes. The one-year data reported continued absence of grade 3 or higher toxicities and reductions in long-term patient-reported outcome measures after MRIdian treatment. Researchers from Amsterdam University Medical Centers enrolled 101 patients and the study is one of the first to research SBRT in a mix of intermediate- and high-risk prostate cancer patients, a population that is challenging to treat. The journal is the official scientific journal of the European Association of Urology.



All patients received MRgRT in five fractions of 7.25 Gy to the target volume using adaptive techniques on the MRIdian. The study did not use implanted markers or tissue spacers between rectum and prostate because treatments were delivered under MR-guidance, thereby eliminating the need for an invasive procedure and potentially reducing associated complications.

Results at 12 months showed that no grade 3 GU or GI toxicities were observed. These results were obtained in a complex clinical cohort (59.4 percent high-risk) and are comparable to what would typically be observed in less-complex populations, pointing to potential benefits of MR-guided SBRT for this higher risk group. Little to no grade 2 was reported by patients at 12-month follow up and, importantly, corresponding bowel problems were reported by only 2 percent of patients.

"SBRT offers significant promise in the treatment of prostate cancer. Our study showcases that MRIdian allowed for optimal target coverage and the use of small planning margins which may directly contribute to the low toxicity observed at one year," said principal investigator Anna Bruynzeel, M.D., Ph.D., Radiation Oncologist at Amsterdam UMC. "Our findings are in contrast to conventional EBRT data, which recently reported a negative effect on bowel function at 12-month follow up. These results reinforce the value of MRIdian's real-time on-table adaptive treatment with automated beam gating for prostate cancer patients."

Amsterdam UMC is pioneering efforts in the use of MRIdian SBRT and the application to treat prostate cancer. Not only is this the largest prospective clinical trial in the use of MRgRT, but also the first prospective clinical trial on MR-guided radiation treatment for prostate cancer without the need for implanted markers in intermediate- to high-risk patients.

"We have the potential to change the course of radiation therapy with a shorter treatment schedule, lower potential costs, and reduction in complications associated with an invasive procedure," said Martin Fuss, M.D., Chief Medical Officer at ViewRay. "MRIdian's capabilities of real-time soft tissue tracking, on-table adaptive dose planning, and automated beam gating provide physicians the confidence and tools they need to deliver a precise and accurate dose while sparing sensitive structures near the target in order to achieve better patient outcomes."

The in-press article can be accessed at <https://linkinghub.elsevier.com/retrieve/pii/S2588931120300614>.

#### **About the Study**

Article in Press in the European Urology Oncology Journal, titled: "Magnetic Resonance-Guided Stereotactic Radiotherapy for Localized Prostate Cancer: Final Results on Patient-Reported Outcomes of a Prospective Phase 2 Study," authored by Shyama U. Tetar, Anna M.E. Bruynzeel, Swie S. Oei, Suresh Senan, Tamara Fraikin, Berend J. Slotman, R. Jeroen A. van Moorselaar, and Frank J. Lagerwaard. According to the study, "In this prospective phase 2 trial in men with localized prostate cancer, the use of stereotactic MRgRT for optimal target coverage allowed the use of small planning margins, a finding that may account for low patient- and clinician-reported toxicity rates at one-year follow up. The absence of grade 3+ GI or GU toxicity is encouraging."

Anna M.E. Bruynzeel has received honoraria from ViewRay, Inc. outside the scope of this study and has served on the advisory board of ViewRay Inc. Suresh Senan has received research grants from ViewRay Inc. Berend J. Slotman has received research grants and honoraria from ViewRay Inc. Frank J. Lagerwaard has received honoraria from ViewRay Inc.

#### **About ViewRay®**

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

#### **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.

#### **About Amsterdam University Medical Centers**

Amsterdam UMC employs more than 15,000 professionals, treating over 350,000 patients per year at both its sites – AMC and VUmc. Working towards a future in which illnesses are prevented and the best treatment made available to all patients, Amsterdam UMC has developed new methods for diagnostics and treatment together with professionals from other renowned national and international institutions. The institute's main focus is on complex patient care and highly-specialized treatment of rare medical conditions. Amsterdam UMC teaches and trains thousands of young people to become doctors, specialists or nurses. Its researchers are clustered in eight research centers so that the institute can achieve its ambition of executing international, cutting-edge research. At Amsterdam UMC, AMC and VUmc are working together on academic patient care, scientific research and teaching and training.

#### **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 2020, and ViewRay's conference calls to discuss its quarterly 2020 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, 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, 2019 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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