FOR IMMEDIATE RELEASE

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FDA CLEARS ISORAY'S GliaSite® TREATMENT FOR BRAIN CANCER

World's Only Liquid Radiation Balloon Catheter Device Treats

Glioblastomas and Metastasized Brain Cancers

Richland, WA (September 12, 2011) - **- IsoRay, Inc. (Amex: ISR) announced today that the FDA has cleared its GliaSite® radiation therapy system, a balloon catheter device used in the treatment of brain cancer.** The clearance was the major step required to return the GliaSite® radiation therapy system to the marketplace. The system's balloon catheter is a landmark technology that allows physicians to treat more brain cancer patients than ever before with internal radiation or brachytherapy.

The GliaSite® radiation system offers a number of advantages in brain cancer treatment. A specified high dose of a liquid radiation source is placed in the areas most likely to contain cancer after brain tumor removal. This form of radiation is less likely to damage healthy brain tissue than other alternatives**. The ability for the tumor to recur is greatly diminished, impacting patient longevity and quality of life.**

IsoRay has exclusive worldwide distribution rights for the GliaSite® radiation therapy system as well as exclusive worldwide licensing rights to Iotrex®, a liquid iodine radiation for use in brain cancer treatment**.** IsoRay undertook a number of steps ranging from improvement in product design, rigorous testing, and new manufacturing techniques including a new balloon manufacturing system before seeking FDA clearance for use**. IsoRay's improved GliaSite® delivery system was found to have exceeded all prior product specifications during the reporting and testing phase.**

Brain cancer is one of the fastest growing cancers and recurrence often proves fatal. Over 575 people a day are diagnosed with brain cancer in the United States alone. No two brain tumors are alike and brain cancers can range from Glioblastomas to metastasized brain cancer. Brain cancer's impact can be devastating with its effect on the vital center that controls a person's thinking, emotions, and movement. These tumors are very difficult to treat. Completely removing a tumor presents complex challenges to minimize damage to the brain. Doctors must also deal with the intricacies of tumors that tend to spread to healthy parts of the brain. Typically, surgeons remove as much as they can of the tumor and then treat the areas surrounding where the tumor was removed with radiation therapy. Chemotherapy is sometimes used as well. Treatment is further complicated by the fact that most cancerous brain tumors recur shortly following removal, and the cancer tends to return near the site of the original tumor.

With the FDA clearance, IsoRay will now be able to move forward in seeking additional regulatory approval for its new liquid form of Cesium-131 internal radiation therapy for the treatment of brain cancer that would be delivered using the GliaSite® system replacing Iotrex. In its current form, IsoRay's patented Cesium-131 internal radiation therapy is demonstrating its value. **Cesium-131's current five year data has the highest cancer free success rate for patients being treated for prostate cancer.** It represents the biggest advancement in internal radiation therapy in twenty years providing several advantages over other internal radiation therapies. Doctors can vigorously treat a variety of cancers with reduced side effects and limited damage to healthy

surrounding tissues and organs compared to other internal radiation therapies**. Cesium-131 radiation therapy impacts longevity and cure rates, can be performed outside a hospital setting, and results in a patient's faster return to normal activities.**

IsoRay CEO Dwight Babcock says the FDA clearance represents another step forward in achieving the Company's goals. "FDA clearance of the GliaSite® system represents a key development in opening the door to further advances that can expand treatment efficacy as we seek clearance for the use of liquid Cesium-131. We have already seen the importance of Cesium-131 internal radiation therapy seeds in effecting survivability and quality of life in the treatment of cancers throughout the body. As a company, we are excited to see expanding adoption in hospitals and medical practices nationwide and internationally. Just as importantly, however, we are cognizant of this crucial milestone for patients who are searching for treatment options and hope in their fight against brain cancer. "

Prior to the Company's acquisition of the **GliaSite®** technology, approximately 500 **GliaSite®** cases were performed annually at some 40 hospitals worldwide. **Babcock says physicians are enthusiastically awaiting Gliasite®'s availability. "With our sales launch expected in the fourth quarter , we know there is great interest and a growing number of inquiries from the marketplace. We are already hearing from doctors who are anxious to access this leading-edge technology to treat their patients and give them more choices," he noted.**

The GliaSite® system has established reimbursement for both in-patient and out-patient settings. In addition to its CMS codes, Cesium-131 is FDA-cleared in seed form for the treatment of prostate, lung, ocular melanoma, brain, colorectal, gynecologic, and head and neck cancer and other cancers throughout the body.

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About IsoRay

IsoRay, Inc., through its subsidiary, IsoRay Medical, Inc., is the sole producer of Cesium-131 brachytherapy seeds, which are expanding brachytherapy options throughout the body. **Learn more about this innovative Richland, Washington company and explore the many benefits and uses of Cesium-131 by visiting www.isoray.com**.

Safe Harbor Statement

Statements in this news release about IsoRay's future expectations, including: the advantages of our Cesium-131 seed, the advantages of the GliaSite® delivery system, whether a liquid form of Cesium-131 will be developed that receives regulatory approval and can be used successfully with the GliaSite® delivery system, whether IsoRay will be able to continue to expand its base beyond prostate cancer, whether IsoRay's Cesium-131 seed will be used to treat additional cancers and malignant disease, whether the use of GliaSite® with Iotrex® or Cesium-131 to treat brain or other cancers will be successful in the initial and any future implants, the timing of IsoRay's sales launch for the GliaSite® delivery system, whether there will be demand for GliaSite® at expected levels, and all other statements in this release, other than historical facts, are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 ("PSLRA"). This statement is included for the express purpose of availing IsoRay, Inc. of the protections of the safe harbor provisions of the PSLRA. It is important to note that actual results and ultimate corporate actions could differ materially from those in such forward-looking statements based on such factors as physician acceptance, training and use of our products, our ability to successfully manufacture, market and sell our products, our ability to manufacture our products in sufficient quantities to meet demand within required delivery time periods while meeting our quality control standards, our ability to enforce our intellectual property rights, whether additional studies are released and support the conclusions of early clinical studies, whether initial implants of Cesium-131 to treat brain or other cancers result in favorable patient outcomes, whether resources are available as needed to develop a liquid form of Cesium-131 and whether such liquid form receives and maintains all required regulatory approvals, whether any liquid form of Cesium-131 is able to be used successfully with the delivery system, patient results achieved when Cesium-131 is used for the treatment of cancers and malignant diseases beyond prostate cancer whether with the GliaSite® delivery system or in another delivery system, successful completion of future research and development activities, and other risks detailed from time to time in IsoRay's reports filed with the SEC.