



FOR IMMEDIATE RELEASE

**Oraya Therapeutics Initiates First Ever Sham-Controlled Study  
of Radiation Therapy for Wet AMD**

NEWARK, CA. January 5, 2010—Oraya Therapeutics, Inc., announced today that enrollment is now underway for the first ever masked and sham-controlled study to demonstrate the efficacy and safety of radiation therapy for the treatment of wet age-related macular degeneration (AMD). The groundbreaking clinical trial is being conducted at seven European sites, and will include a minimum of 150 patients, with approximately one third of those receiving a sham exposure and the remainder receiving radiation dosing of either 16 or 24 Gray (GY).

All patients will have standard of care anti-VEGF drug therapy, and the trial is designed and powered to measure the effect of the radiation adjunct on vision outcomes and on the frequency of anti-VEGF injections. Trial endpoints will be evaluated one year post radiation treatment. The radiation dose is delivered using Oraya's IRay™ system, a proprietary non-invasive low energy stereotactic X-ray platform that has been in development since early 2007. Over 60 patients have already been treated in a Phase 1 study of the device, and results from that study led to the design and initiation of this newly announced trial.

In commenting on the trial, Jim Taylor, president & CEO of Oraya says, "We are pleased to have reached this important milestone for the company, and even more excited to demonstrate conclusively the value of this promising new therapeutic approach for the treatment of AMD. Our employees, investors and clinical advisors have all made exceptional commitments and contributions to this

endeavor, and it is gratifying to see that we now have the opportunity to conduct such an important and scientifically sound clinical study.”

The IRay system is an investigational stereotactic radiosurgical device designed specifically to treat diseases of the eye. The single organ focus of Oraya's technology enables precise delivery of low-energy X-rays to treat wet AMD. Designed to maximize patient comfort and precision, the IRay system utilizes a vacuum-coupled contact lens interface, the I-Guide™, which holds the eye to maintain stability during treatment, while detecting eye motion. A gating system, which automatically shuts down the device in case of misalignment due to patient movement, is also featured. Because the radiation delivered is low-voltage, comparable to a chest or dental X-ray, the IRay is suitable for use in a typical ophthalmology office setting. The entire patient treatment process requires only a topical anesthetic, and lasts 15 to 20 minutes.

In discussing the European trial, Darius Moshfeghi, M.D., associate professor of ophthalmology at Stanford University, and a clinical advisor to Oraya, commented that “Data from the Phase 1 study, with over a year follow-up to date, clearly show potential effects that are outside those seen in current day to day practice. With an excellent safety profile so far, it will be very interesting to see how the [IRay] therapy performs in this well designed and controlled trial.”

Peter Kaiser, M.D., of the Cole Eye Institute at the Cleveland Clinic and a recognized expert on new therapies for AMD, notes that “Combination therapies as adjuncts to anti-VEGF therapy are showing great promise to improve the overall treatment options and outcomes for wet AMD patients. The growing body of data from radiation therapy studies during the last few years has become of significant interest, with results suggesting that both patient outcome and treatment burden and cost could be positively impacted.” Dr. Kaiser participated

in the design of Oraya's European protocol, and remains an active advisor to the company.

Additional information about Oraya's randomized, masked, sham-controlled study of radiotherapy for wet AMD, currently enrolling in Europe, can be found at <http://www.orayainc.com/clinicaltrials.asp>, and by searching [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for identifier NCT01016873.

### **About Oraya Therapeutics**

Oraya Therapeutics, Inc. is a privately-held company developing innovative and non-invasive therapies for diseases of the eye. Founded in 2006, Oraya is funded by Essex Woodlands Health Ventures, Synergy Life Science Partners, Scale Venture Partners and Domain Associates.

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