Oraya Therapeutics INTREPID Study Demonstrates Two-year Safety and Effectiveness of Non-invasive Therapy for Wet AMD

Ideal responders maintain 45 percent mean reduction in anti-VEGF injections

NEWARK, Calif. Sept. 25, 2013 — Oraya® Therapeutics, Inc. announced today the two-year results of its INTREPID study of Oraya Therapy™ Stereotactic Radiotherapy for the treatment of wet age-related macular degeneration (AMD). These results provide continued evidence of a favorable safety profile and the therapy's ability to reduce the frequency of anti-vascular endothelial growth factor (VEGF) injections in the eye.

The broadly inclusive cohort of non-naïve wet AMD patients continued to receive the benefit of a 25 percent mean reduction in anti-VEGF injections over two years. Patients identified in the first year as ideal response candidates maintained an impressive 45 percent mean reduction in anti-VEGF injections through the two-year visit, with superior vision to the non-treated group. In addition, the overall safety profile was positive, with only one percent of treated patients showing evidence of micro-vascular abnormalities due to radiation that could affect vision outcomes.

"A treatment that offers the prospect of fewer injections will be welcomed by clinicians and patients alike. Importantly, if we select the right patients, vision appears to be better than with anti-VEGF monotherapy. The safety at two years is also encouraging, in that most micro-vascular changes were located away from the fovea, and so did not have an impact on vision," said Timothy L. Jackson, PhD, FRCOphth, King's College Hospital, London, lead investigator for the INTREPID trial.

The ideal response candidates were identified at year one through post-hoc analysis as patients with significant fluid in the retina at baseline and a lesion size of 4 mm or less in greatest linear dimension, which corresponds to the diameter of X-ray beam spot centered on the fovea. The majority of existing and new wet AMD patients meet these criteria, indicating that the benefits of Oraya Therapy are broadly applicable to the wet AMD patient population.

"Patients are eager for new Wet AMD treatments that can reduce injections while maintaining or improving vision. We look forward to bringing Oraya Therapy to more patients as we expand availability in the European market," said Oraya Therapeutics President and CEO Jim Taylor. "We

welcome the positive year two safety data from the INTREPID trial along with the ability to identify patients who will receive the best outcomes,"

The full two-year efficacy and safety results will be presented at EURETINA 2013 in Hamburg, Germany this week. Timothy L. Jackson will present "Stereotactic radiotherapy for the treatment of neovascular age-related macular degeneration: year 2 results of the INTREPID trial" on Thursday, Sept. 26 at 8:46 a.m. Professor Usha Chakravarthy, MBBS, PhD, FARVO, Queens University of Belfast, will present "Characteristics of radiation induced microangiopathy in the treatment of wet AMD" on Friday, Sept. 27at 8:24 a.m. Also during EURETINA, a special seminar will take place on Saturday, Sept. 28 from 10:00-11:00 a.m., featuring talks detailing the efficacy, safety and clinical experience of the Oraya Therapy. To register to attend, visit www.euretina.org/hamburg2013/satellite-meetings.asp.

The INTREPID study was the first trial to evaluate the effectiveness and safety of the Oraya Therapy in conjunction with as-needed anti-VEGF injections, and is the only sham-controlled double-masked trial to assess stereotactic radiotherapy for wet AMD. One-year results of the trial were published in the September 2013 edition of the leading peer-reviewed journal *Ophthalmology*. The study met primary endpoints, showing that Oraya Therapy significantly reduces the need for anti-VEGF injections for patients with Wet AMD, and demonstrated a favorable safety profile. A total of 21 sites in five European countries participated in the trial, with a total enrollment of 230 patients; 212 patients were followed through the two-year visit.

The Oraya Therapy uses low-energy, highly targeted X-rays for the treatment of wet AMD. Intended as a one-time procedure, it is non-invasive, rapid, comfortable for the patient and easy for a trained operator to perform. The total procedure time is typically less than 20 minutes. The IRay™ radiotherapy system's delivery approach, targeting algorithm, unique eye stabilization and tracking methods are all proprietary.

Wet AMD, a disease characterized by abnormal growth of blood vessels in the macula, is responsible for the vast majority of severe vision loss in the industrialized world. If left untreated, it can quickly lead to the rapid deterioration of visual acuity and blindness. While there is no cure for wet AMD, the expense and burden of current treatment methods, which involve regular injections into the eye, have driven the development of novel approaches such as the Oraya Therapy.

The IRay is a CE marked medical device. The IRay is not available for sale in the United States. For more information, please visit www.orayainc.com.

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About Oraya Therapeutics:
Oraya Therapeutics, Inc. is a privately held company developing innovative and non-invasive therapies for diseases of the eye. The company was founded in 2007. Its investors include Essex Woodlands Health Ventures, Domain Associates, Scale Venture Partners, and Synergy Life Science Partners. More information about Oraya Therapeutics can be found at www.orayainc.com**.**

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