# Oraya Therapeutics' AMD Radiotherapy Device Receives New Indication of Use for Choroidal Metastases

## *Extended CE Mark brings new treatment option to patients in the United Kingdom, Germany and Switzerland*

NEWARK, Calif., March 3, 2015— Oraya Therapeutics announced today that the Oraya IRay® Radiotherapy system has received a CE Mark extension for the treatment of choroidal metastases, a cancer in the eye, originating most commonly from primary sites in the breast or lung. This new indication of use expands upon Oraya's prior approval for the treatment of wet Age Related Macular Degeneration (AMD) and may offer patients in the United Kingdom, Germany and Switzerland a new treatment option for a vision-threatening condition.

"This oncology indication demonstrates the breadth of possibilities that are enabled by the proprietary aspects of the IRay platform," Oraya CEO Jim Taylor said. "While Oraya's primary focus remains on treating wet AMD, we continue to identify and evaluate other uses of the technology that may benefit patients and clinicians."

Unlike ocular melanomas, choroidal metastases can grow quickly and may require prompt treatment to prevent vision loss. While chemotherapy may be used, radiation therapy is typically the preferred treatment using either plaque brachytherapy or external beam radiation therapy (EBRT), invasive procedures requiring therapy regimens conducted over days or weeks.

Oraya's IRay Radiotherapy system utilizes a robotically positioned low-energy X-ray source to enable the delivery of a precise dose of radiation to the back of the eye in a 15-20 minute non-invasive procedure. The stereotactic radiation delivery and the use of low energy X-rays offer the potential for treatment of choroidal metastases without surgery and the related patient burden of multiple treatment sessions.

"The precision and simplicity enabled by the Oraya technology offer potential advantages compared to existing alternatives," said Prof. Bornfeld, professor in ophthalmology and head of the department for posterior segment diseases at the University of Essen, Germany. "There is real opportunity to evolve this technology further, providing a meaningful addition to our clinical treatments."

Professor Ian Rennie, M.B., ChB, F.R.C.S., consultant ophthalmologist at the Sheffield Hospitals NHS Foundation Teaching Trust in the United Kingdom, and expert in the treatments of ocular cancers,

commented, "I welcome this development because of the opportunity it provides to evaluate this form of radiotherapy in the treatment of certain vision-threatening tumors. If proven effective, this modality would provide a simple and safe alternative to conventional radiotherapy."

"Professors Bornfeld and Rennie, both globally respected experts in the field of ocular radiation therapy, have provided invaluable guidance to Oraya," Taylor added. "We have been fortunate to work closely with them, and we look forward to ongoing developments that will further advance and extend the IRay system capabilities."

The Oraya IRay Radiotherapy system received CE certification for the treatment of wet AMD in March 2010, and the company began actively commercializing Oraya Therapy in 2014. Oraya Therapy is now available at 11 treatment centers located in Germany, the United Kingdom and Switzerland, and with an equal number in the active planning pipeline. In December 2014, Carl Zeiss Meditec AG and Oraya entered into a collaboration agreement under which Carl Zeiss Meditec will provide funding to Oraya over a period of up to two years for the implementation of Oraya's growth strategy, particularly its expansion in Europe.

In the U.S., the IRay System is an investigational device and is not available for sale.

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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 Carl Zeiss Meditec AG. More information about Oraya Therapeutics can be found at www.orayainc.com.

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