Pre-clinical Evaluation of Oraya's IRay System for Delivery of Microcollimated Pars Plana External Beam Radiation to the Eye.

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Purpose:

To evaluate an investigational stereotactic radiosurgical system delivering microcollimated X-rays through pars plana for choroidal neovascularization due to age-related macular degeneration.

Methods:

Oraya's IRay is an office-based device, which delivers low energy X-rays to the macula. It combines a robotically positioned 100 keV X-ray tube, eye alignment and tracking, treatment planning, and automated safety features. The beams are highly collimated, with a diameter of 3.5 mm on the sclera and 4 mm on the retina. Clinically, IRay delivers up to 22 Gy to the 90% isodose, using 3 sequential beams which pass through the sclera and overlap at the macula.

Animal studies are being completed for verification of system targeting and safety. Yucatan mini-swine (12 eyes) were randomized to ten eyes irradiated on Day 1, and two eyes as untreated controls. Treated eyes received up to 90 Gy to the retina, and up to 90 Gy to each scleral entry point, delivered within 10 minutes. Eye exams, fundus photography, fluorescein angiography (FA), and spectral domain optical coherence tomography (SD-OCT) were obtained at Days 7, 30, 60 and 90. Indocyanine green angiography (ICG) was done at Day 90.

Results:

Through Day 90 interim analysis, treatment was well-tolerated, with no anomalies to outer structures, including the lens. Fundus evaluation revealed no abnormalities in the clinically relevant doses of 16 or 24 Gy. Beginning at Day 30, retinal lesions were noted in the 42, 60 and 90 Gy eyes as circular pale areas on ophthalmoscopy and fundus photography. FA showed late staining of the higher-dose lesions beginning at Day 30, with no hemorrhages, cotton wool spots, or vascular occlusions/sheathing. Capillary closure with underlying choroidal hypoperfusion was seen on ICG in the 90 Gy group. SD-OCT of the 60 and 90 Gy eyes indicated a defined lesion, with loss of photoreceptors, and retinal thinning.

Conclusions:

Pre-clinical evaluation of Oraya's IRay system confirms that the device is able to accurately deliver X-rays to the retina through the pars plana while avoiding exposure to surrounding critical structures, such as the lens and optic nerve. No observable adverse effects are noted at clinically relevant doses.