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SUBRETINAL IMPLANTATION OF A BIOENGINEERED EMBRYONIC STEM CELL-DERIVED RETINAL PIGMENT EPITHELIUM MONOLAYER IN DRY AGE RELATED MACULAR DEGENERATION

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Non-neovascular AMD (NNAMD) can result in severe vision loss secondary to loss of the retinal pigmented epithelial (RPE) cell layer and geographic atrophy (GA). There is no treatment for GA. As a possible intervention, a bioengineered implant was developed consisting of pluripotent stem cell-derived RPE cells polarized on an ultrathin parylene membrane which has the diffusion properties of the native Bruch's membrane. A prospective, open-label phase 1/2a study is underway to assess the safety and activity of the bioengineered subretinal implant in subjects with vision loss from advanced NNAMD and GA. Key inclusion criteria included diagnosis of NNAMD with GA, pseudophakic status, best-corrected visual acuity of 20/200 or worse (cohort1) or 20/80 to 20/400 (cohort 2) and age 55-85 years. A single investigational implant has been surgically delivered to the area of RPE loss in the worse eye of each subject. Surgical delivery involved pars plana vitrectomy, subretinal dissection and implantation of the implant using a custom-made insertion device. Patients were administered a 60-day course of tacrolimus immunosuppression. The primary outcome measure is safety at 1-year post-implant. Secondary endpoints include assessment of ETDRS visual acuity, microperimetry based fixation testing and optical coherence tomography OCT). Immunological monitoring is being conducted to assess antibody mediated immune responses to HLA antigens on the allogeneic implanted RPE cells. The clinical trial is being conducted at 6 clinical trial sites in southern California and Arizona. Enrolment is now complete. Baseline imaging and clinical examination confirmed that each subject had a large area of GA exhibiting decreased pigmentation involving the fovea. OCT demonstrated an appropriately placed CPCB-RPE1 implant in the subretinal space of GA. An update on the clinical trial will be provided at the meeting. Support for this program was provided by the California Institute of Regenerative Medicine and Santen Pharmaceutical Co, Ltd.

Biography

Jane S Lebkowski has received her PhD in Biochemistry from Princeton University in 1982 and completed a Postdoctoral Fellowship at the Department of Genetics, Stanford University. He has been actively involved in the development of cell and gene therapies since 1986 and is President of Regenerative Patch Technologies (RPT), a biotechnology firm developing stem cell-based implants targeting restoration of retinal function in patients with macular degeneration. From 2013-2017, he has served as the President of R&D at Asterias Biotherapeutics Inc, where she headed all preclinical, product, regulatory, and clinical development of Asterias' regenerative medicine products. Prior to joining Asterias, he was Senior Vice President of Regenerative Medicine at Geron Corporation and led Geron's human embryonic stem cell program from 1998-2012. He has published over 80 peer reviewed publication. He has served on the boards of the American Society of Gene and Cell Therapy and the International Society for Stem Cell Research.

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