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Regenerative Patch Technologies Provides Update on Phase 1/2a Clinical Trial of Stem Cell-Engineered Implant for the Treatment of Dry Age-Related Macular Degeneration

Long-term Survival of Implanted Cells Documented; Improvements in Vision Observed in Legally-Blind Eyes

Menlo Park, CA, June 28, 2021 (PR Newswire) Regenerative Patch Technologies LLC (RPT) announced today the presentation of results from its Phase 1/2a clinical trial of the CPCB-RPE1 implant for advanced, dry age-related macular degeneration. The presentation entitled “Phase 1/2a Clinical Assessment of a Bio-engineered RPE Cell-Based Implant for the Treatment of Advanced Dry-Age-Related Macular Degeneration” was given at the International Society of Stem Cell Research 2021 annual meeting by Jane Lebkowski, Ph.D., President of RPT. The presentation can be found at www.regenerativepatch.com.

Dr. Lebkowski described the latest results from RPT’s Phase 1/2a clinical trial (www.clinicaltrials.gov. NCT02590692) in geographic atrophy, the advanced form of dry age-related macular degeneration (AMD). The CPCB-RPE1 implant, a bio-engineered scaffold supporting a layer of stem cell-derived, retinal pigmented epithelial (RPE) cells, was delivered to the worst eye of 15 subjects with geographic atrophy. All treated eyes were legally-blind having a best corrected visual acuity (BCVA) of 20/200 or worse. The implant was delivered safely to the area of geographic atrophy in the outpatient setting and remained stably in place throughout the trial. Refinements to the implantation procedure during the trial further improved its efficiency and safety profile.

Subjects in the trial were also assessed for visual function. At an average of 34 months post-implantation (range 12-48 months), 27% (4/15) showed a greater than 5 letter improvement in BCVA and 33% (5/15) remained stable with a BCVA within 5 letters of baseline value. The improvements ranged from 7-15 letters or 1-3 lines on an eye chart. In contrast, BCVA in the fellow, untreated eye declined by more than 5 letters (range 8-

21 letters or 1-4 lines on an eye chart) in 80% (12/15) of subjects. There was no improvement in BCVA in the untreated eye of any subject.

“The improvements in best corrected visual acuity observed in some eyes receiving the implant are very promising, especially considering the very late stage of their disease”, stated Dr. Mark Humayun, founder and co-owner of RPT, Director of the USC Ginsburg Institute for Biomedical Therapeutics and Co-Director of the USC Roski Eye Institute, Keck Medicine of USC. “Improvements in visual acuity are exceedingly rare in geographic atrophy as demonstrated by the large decline in vision in many of the untreated eyes which also had disease. There are currently no approved therapies for this level of advanced dry age-related macular degeneration”.

The CPCB-RPE1 implant utilizes unmatched, “allogeneic” RPE cells as one of its two main components. Subjects in the trial received a short course of immunosuppression shortly before and immediately after implantation. There were no clinical signs of rejection of the implant and subjects did not mount an antibody response to the implanted cells.

Eyes from a subject who passed away over two years after implantation were examined histologically and showed the presence of viable, functioning RPE cells associated with the implant in the treated eye. “The results suggest that even with a short immunosuppression protocol, implanted allogeneic RPE cells can survive and function long-term in the retina”, said Dr Amir Kashani, lead investigator on the clinical trial.

“The observed long-term cell survival has positive implications for the use of an allogeneic stem cell product for retinal disease. Use of allogeneic cells enables large-scale manufacturing procedures to produce the implant, simplifying the logistics and decreasing the costs of its manufacture,” said Dr Dennis Clegg, founder of RPT and Professor at the University of California Santa Barbara. “RPT has also developed a cryopreserved formulation of the implant which will allow global distribution of the implant”

“The collective data from the phase 1/2a clinical trial demonstrate the safety and tolerability of the implant along with providing signals of sight -improving activity. The data demonstrate that improvement of vision in subjects with geographic atrophy is attainable and the improvements observed to date are superior to drug therapies currently in late-stage clinical development which only facilitate delay in disease progression. The data positions RPT to proceed to a Phase 2b clinical trial to advance development of the product”, said Dr Jane Lebkowski. “We greatly appreciate funding

from the California Institute of Regenerative Medicine and Santen Pharmaceuticals for the Phase 1/2a clinical trial."

About Regenerative Patch Technologies and the CPCB-RPE1 Implant

Regenerative Patch Technologies LLC is a clinical-stage company developing a stem cell-based implant technology for the treatment of retinal diseases. The CPCB-RPE1 implant, RPT's lead product, is a bio-engineered implant consisting of stem cell-derived, mature, polarized retinal pigmented epithelial (RPE) cells on an ultrathin synthetic parylene membrane. The implant is designed to replace the retinal pigmented epithelium and Bruch's membrane in the eye that degenerate in dry age-related macular degeneration. The technology to produce the CPCB-RPE1 implant is exclusively licensed to RPT from the University of Southern California, the California Institute of Technology and UC Santa Barbara.

About Dry Age-Related Macular Degeneration

Dry age-related macular degeneration is the most common form of age-related macular degeneration, occurring in 90% of people that have AMD. The advanced dry form of age-related macular degeneration, geographic atrophy, is the leading cause of legal blindness in adults affecting 10-20% of people in the United States over the age of 65.

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