Lineage Cell Therapeutics to Host Webinar With Therapeutic Area Experts to Discuss Retinal Tissue Restoration Observed in Dry AMD Patients Treated With OpRegen®

June 3, 2021

Webinar Scheduled for June 10, 2021 at 4pm Eastern Time / 1pm Pacific Time

CARLSBAD, Calif.--(BUSINESS WIRE)--Jun. 3, 2021-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, announced today that it plans to host a webinar featuring external therapeutic area experts in age-related macular degeneration (AMD), on June 10, 2021 at 4pm ET /1pm PT. Lineage recently reported that restoration of retinal tissue has been observed in three patients enrolled in the Company's Phase 1/2a study of its lead product candidate, OpRegen, an allogeneic retinal pigment epithelium (RPE) cell transplant therapy in development for the treatment of AMD with geographic atrophy (GA), or dry (atrophic) AMD. These new findings occurred in three of the four better baseline vision (Cohort 4) patients for whom surgeons successfully covered the majority of the area of atrophy with a suspension of OpRegen RPE cells. Outer retinal layer restoration, which was observed using high-resolution Optical Coherence Tomography (OCT), was evidenced by the presence of new areas of RPE monolayer with overlying ellipsoid zone, external limiting membrane, and outer nuclear layer, which were not present at the time of baseline assessment. These findings suggest integration of the new RPE cells with functional photoreceptors in areas that previously showed no presence of any of these cells. These effects were most prominent in the transitional areas around the primary area of GA. The webinar will feature therapeutic area experts who will discuss these findings in detail, including a review of anatomical improvements, functional activity, and additional results of treatment with OpRegen. Interested parties can access the webinar on the Events and Presentations section of Lineage's website.

Therapeutic Area Experts, External Reviewers & Contributors

Eyal Banin, M.D., Ph.D., Director, Center for Retinal and Macular Degenerations (CRMD), Department of Ophthalmology, Hadassah-Hebrew University Medical Center.

Dr. Banin is a graduate of the Hebrew University-Hadassah School of Medicine, holds a Ph.D. in Neurobiology from the Hebrew University, and completed his ophthalmology residency at Hadassah Medical Center. Following a post-doctoral and medical retina fellowship at the University of Pennsylvania's Scheie Eye Institute in Philadelphia, he was appointed head of the Medical Retina Service and the CRMD at Hadassah. His main clinical and research focus is in the field of retinal and macular degenerations, including the development and application of novel cell- and gene-based therapies for these diseases. The recipient of many research grants from Israeli and foreign institutions, Dr. Banin has authored and published over 150 peer-reviewed articles in leading medical and scientific journals.

Jordi Monés, M.D., Ph.D., Director, Institut de la Màcula, Director and Principal Investigator, Barcelona Macula Foundation: Research for Vision.

Dr. Monés is an ophthalmologist, macula and vitreoretinal specialist, and macular and retinal degeneration researcher. Dr. Monés earned his medical degree at the University of Barcelona and subsequently specialized in ophthalmology at Barraquer Ophthalmology Centre. He completed his retinal specialist training at the Massachusetts Eye and Ear Infirmary at Harvard University, and at Hospital San José, Monterrey Institute of Technology and Higher Education. He earned his PhD degree in Medicine and Surgery at the University of Barcelona. Dr Monés is dedicated to fighting blindness by supporting and conducting research in retinal disease. For the last 15 years he has been one of the foremost researchers involved in clinical trials for the treatment of age-related macular degeneration. He is currently conducting Phase I, II and III clinical trials. His work has been widely published in scientific journals and he has given more than 200 presentations at international congresses. He is a member of 12 scientific societies.

Brandon Lujan, M.D., Associate Professor of Ophthalmology, School of Medicine, OHSU Casey Eye Institute.

Dr. Lujan is a medical retina specialist, scientist, and Director of the Casey Reading Center. Dr. Lujan's area of expertise is Optical Coherence Tomography (OCT) retinal imaging, and he is the first-named inventor and co-developer of Directional OCT, a technique and device capable of creating optical contrast in photoreceptors. Dr. Lujan has published and spoken internationally on diagnosis and management of macular diseases and has brought that expertise to bear on clinical trials. He is the creator of OCTMD, an educational resource focused on the present and future of OCT. Dr. Lujan is a member of the Macula Society, Retina Society, the Association for Research and Vision in Ophthalmology, and the American Society of Retina Specialists.

Christopher D. Riemann, M.D., Vitreoretinal Surgeon and Fellowship Director, Cincinnati Eye Institute (CEI) and University of Cincinnati School of Medicine.

In collaboration with the other retinal surgeons at CEI, Dr. Riemann is a principal investigator or co-investigator for many Phase II and Phase III clinical trials. He specializes in medical and surgical vitreoretinal diseases including diabetic retinopathy, macular degeneration, retinal detachment, retinopathy of prematurity, vascular diseases of the retina, uveitis, histoplasmosis, complications of anterior segment surgery, endoscopic posterior segment surgery, and ocular trauma. Dr. Riemann is a member of the American Society of Retina Specialists, American Academy of Ophthalmology, Ohio State Medical Association, Cincinnati Academy of Medicine, Cincinnati Ophthalmology Society, and the Association for Research in Vision and Ophthalmology. His original research in the fields of Ophthalmology, Cardiology, and Endocrinology has been published in international peer reviewed scientific journals and has been presented at national scientific meetings. Dr. Riemann has several patents for innovative surgical technologies and enjoys sharing his passion for the blend of engineering and medicine.

Michael S. Ip, M.D., Professor, Department of Ophthalmology at the David Geffen School of Medicine at the University of California - Los Angeles.

Dr. Ip is a member of the Doheny Eye Institute and currently serves as the Medical Director of the Doheny Image Reading Center. His research focuses on the design and conduct of clinical trials investigating treatments for diabetic retinopathy, AMD, and retinal venous occlusive disease and other retinal diseases. Dr. Ip has assisted with the collection, analysis, and dissemination of important primary and secondary outcomes in ophthalmic clinical trials. In 2003, Dr. Ip was selected to serve as the national protocol chair for the clinical trial conducted by the Diabetic Retinopathy Clinical Research Network (DRCR.net) comparing focal/grid photocoagulation and intravitreal triamcinolone for diabetic macular edema (protocol B). This was a landmark study and changed practice patterns in the field of ophthalmology. In 2003, his independent and investigator-initiated research group received a U-10 cooperative agreement award from the National Eye Institute, National Institutes of Health to conduct the Standard Care vs Corticosteroid for Retinal Vein Occlusion (SCORE) Study. This was a multicenter, randomized, NIH-defined phase 3 trial which led to over 15 publications in the peer-reviewed literature and provided much needed Level 1 evidence to guide our management of retinal venous occlusive disease. In 2013, this group received funding from the NEI to conduct the SCORE2 Study. The SCORE2 Study is an NIH-defined phase 3 clinical trial designed to evaluate the comparative efficacy and safety of bevacizumab versus aflibercept for the treatment of macular edema secondary to central retinal vein occlusion. It has been designed to answer several questions of significant public health importance. Currently, this study group has extended the SCORE2 follow up phase to evaluate long-term safety and efficacy outcomes in central retinal vein occlusion.

Allen C. Ho, M.D. FACS, Wills Eye Hospital Attending Surgeon and Director of Retina Research, Professor of Ophthalmology, Thomas Jefferson University.

Dr. Ho maintains special interests in macular diseases, diabetic retinopathy, surgical retinal diseases and clinical trials investigating new treatments for vitreoretinal diseases including gene and cell therapies and new surgical drug delivery devices and techniques. His experience includes collaborative translational and clinical trial clinical research with expertise in study design, methodological testing, data analyses, surgical instrumentation and procedure development, execution and communication of these studies and their study results. He is the current President of The Retina Society and serves on its Executive Committee. Dr. Ho has been Study Chair, Steering Committee Member or Principal Investigator of over 50 clinical trials. Dr. Ho has served on the US FDA Ophthalmic Device Panel, American Academy of Ophthalmology (AAO) Ophthalmic Retina Technology Assessment Committee, AAO Retina Measures Group, AAO IRIS Registry Committee and is past Chair of the AAO Retina Subspecialty Days and Vail Vitrectomy meetings. Through the Wills Eye Hospital Retina Fellowship he has mentored over 60 retina fellows and international research trainees. Dr. Ho has authored over 200 peer reviewed publications and several textbooks and is Editor-in-Chief of Current Opinion in Ophthalmology and Chief Medical Editor of Retina Today.

About OpRegen

OpRegen is currently being evaluated in a Phase 1/2a open-label, dose escalation safety and efficacy study of a single injection of human retinal pigment epithelium cells derived from an established pluripotent cell line and transplanted subretinally in patients with advanced dry AMD with GA. The study enrolled 24 patients into 4 cohorts. The first 3 cohorts enrolled only legally blind patients with Best Corrected Visual Acuity (BCVA) of 20/200 or worse. The fourth cohort enrolled 12 better vision patients (BCVA from 20/65 to 20/250 with smaller mean areas of GA). Cohort 4 also included patients treated with a new “thaw-and-inject” formulation of OpRegen, which can be shipped directly to sites and used immediately upon thawing, removing the complications and logistics of having to use a dose preparation facility. The primary objective of the study is to evaluate the safety and tolerability of OpRegen as assessed by the incidence and frequency of treatment emergent adverse events. Secondary objectives are to evaluate the preliminary efficacy of OpRegen treatment by assessing the changes in ophthalmological parameters measured by various methods of primary clinical relevance. OpRegen is a registered trademark of Cell Cure Neurosciences Ltd., a majority-owned subsidiary of Lineage Cell Therapeutics, Inc.

About Age-Related Macular Degeneration

Age-related macular degeneration (AMD) is an eye disease that can blur the sharp, central vision in patients and is the leading cause of vision loss in people over the age of 60. There are two forms of AMD: dry (atrophic) AMD and wet (neovascular) AMD. Dry (atrophic) AMD is the more common of the two forms, accounting for approximately 85-90% of all cases. In atrophic AMD, parts of the macula get thinner with age and accumulations of extracellular material between Bruch's membrane and the RPE, known as drusen, increase in number and volume, leading to a progressive loss of central vision, typically in both eyes. Global sales of the two leading wet AMD therapies were in excess of $10 billion in 2019. Nearly all cases of wet AMD eventually will develop the underlying atrophic AMD if the newly formed blood vessels are treated correctly. There are currently no U.S. Food and Drug Administration, or European Medicines Agency, approved treatment options available for patients with atrophic AMD.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs. Lineage’s programs are based on its robust proprietary cell-based therapy platform and associated in-house development and manufacturing capabilities. With this platform Lineage develops and manufactures specialized, terminally differentiated human cells from its pluripotent and progenitor cell starting materials. These differentiated cells are developed to either replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury or administered as a means of helping the body mount an effective immune response to cancer. Lineage’s clinical programs are in markets with billion dollar opportunities and include three allogeneic (“off-the-shelf”) product candidates: (i) OpRegen ®, a retinal pigment epithelium transplant therapy in Phase 1/2a development for the treatment of dry age-related macular degeneration, a leading cause of blindness in the developed world; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; and (iii) VAC2, an allogeneic dendritic cell therapy produced from Lineage’s VAC technology platform for immuno-oncology and infectious disease, currently in Phase 1 clinical development for the treatment of non-small cell lung cancer. For more information, please visit www.lineagecell.com or follow the Company on Twitter @LineageCell.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210603005234/en/

Lineage Cell Therapeutics, Inc. IR
Ioana C. Hone
(ir@lineagecell.com)
(442) 287-8963

Solebury Trout IR

Gitanjali Jain Ogawa
(Gogawa@soleburytrout.com)
(646) 378-2949

Russo Partners – Media Relations
Nic Johnson or David Schull
Nic.johnson@russopartnersllc.com
David.schull@russopartnersllc.com
(212) 845-4242

Source: Lineage Cell Therapeutics, Inc.