Lineage Cell Therapeutics Reinitiates Patient Enrollment in Clinical Study of OpRegen® for the Treatment of Dry AMD With Geographic Atrophy

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First OpRegen Patient Dosed at Cincinnati Eye Institute

CARLSBAD, Calif.--(BUSINESS WIRE)--Jun. 18, 2020-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage cell therapy company which manufactures and transplants specific cell types to treat diseases and serious medical conditions, today announced that it has restarted patient enrollment in a Phase 1/2a clinical study of its lead product candidate, OpRegen®, a retinal pigment epithelium (RPE) cell transplant therapy currently in development for the treatment of dry age-related macular degeneration (AMD), following a temporary pause in enrollment as a result of the COVID-19 pandemic. The first patient dosed in the re-start was at Cincinnati Eye Institute (CEI) under the direction of principal investigator Christopher D. Riemann, M.D., Vitreoretinal Surgeon and Fellowship Director, CEI and University of Cincinnati School of Medicine. CEI is a global leader in ophthalmology research and a clinical site where local health and safety regulations recently enabled and cleared clinical study recruitment and treatment. The patient enrolled at CEI was administered Lineage's new thaw-and-inject formulation of OpRegen with Gyroscope Therapeutics' Orbit Subretinal Delivery System (SDS). The Company anticipates that it will complete enrollment of the last 3 patients in Cohort 4 of the OpRegen clinical study in the third quarter of 2020.

"OpRegen is a promising candidate for the future treatment of dry AMD and I am excited to have dosed the first patient at our institute," stated Christopher D. Riemann, M.D. "Delivering OpRegen RPE cells to the subretinal space using the Orbit SDS was straightforward and appears to offer superior dose control and safety compared to traditional delivery methods. We have resumed our patient screening efforts and I look forward to enrolling additional patients into the study as soon as possible."

"We are pleased to safely resume patient enrollment in our OpRegen study under the direction of Dr. Riemann at CEI," stated Brian M. Culley, Lineage CEO. "Data collected from the OpRegen program continues to support the use of our cells in dry AMD with GA, particularly after we moved into treating patients with less advanced disease. Additionally, we recently announced the first known finding of retinal tissue regeneration alongside improvements in the progression of geographic atrophy, visual acuity, and reading speeds in some patients. With enrollment once again underway, our immediate objective is to treat and monitor the final three patients in Cohort 4 of the study and utilize these data to direct our clinical, regulatory, and partnership discussions. Our goal is to combine the best cell line, the best production process, and the best delivery system, to position OpRegen as the front-runner in the race to address the unmet need in the potential billion-dollar dry AMD market."

Recently, Lineage reported the first known finding of retinal tissue regeneration in a patient receiving OpRegen for the treatment of atrophic dry AMD. This unprecedented finding supports the view that dry AMD is not an irreversible, degenerative condition and that some portion of diseased retinal tissue may be recoverable in atrophic end-stage disease patients. The loss of RPE cells over time creates progressively larger areas of geographic atrophy (GA) in the adult retina, leading to impaired vision or complete blindness. Humans lack the innate ability to regenerate retinal tissue and replace lost retina cells, which has led to a presumption that progression of GA may someday be slowed or halted but cannot be reversed. The unique finding from the ongoing OpRegen clinical trial supports a different view, in which an RPE cell transplant can potentially replace or rescue retinal cells in patients who suffer from retinal lesions or degeneration. Lineage has reported evidence from a patient with atrophic end-stage disease who received a transplant of allogeneic RPE cells and showed substantial restoration of retinal tissue within the area of GA. Specifically, the area of GA assessed at 9 months was approximately 25% smaller than the patient's pre-treatment baseline. These findings were initially observed by an independent external advisor using multiple imaging technologies and were subsequently confirmed by the reading center and additional experts in the field of retinal imaging.

The Company has also observed evidence of benefit in some patients, including increases in Best Corrected Visual Acuity (BCVA), reduction in the growth of GA and increases in reading speed. The addition of signs of retinal tissue regeneration provides further support that OpRegen may be a viable treatment for the millions of individuals living with dry AMD, one of the leading causes of vision loss in the world.

About the OpRegen Phase 1/2a Clinical Study

This is 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 will enroll patients into 4 cohorts, with 18 of 21 expected patients enrolled to date. The first 3 cohorts enrolled solely legally blind patients, with best corrected visual acuity (BCVA) of 20/200 or worse. The fourth cohort, which is currently enrolling, will include patients with vision ranging from 20/250 to as high as 20/64. Cohort 4 also includes patients treated with one of two formulations of OpRegen, (i) a formulation which required preparation of cells one day prior to use in a dose preparation laboratory; or (ii) a new "off-the-shelf" or "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. Additionally, for the patients in Cohort 4 that receive subretinal delivery of OpRegen utilizing Gyroscope Therapeutics' Orbit Subretinal Delivery System (Orbit SDS), objectives will include the evaluation of the safety of delivery of OpRegen using the Orbit SDS.

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) VAC, an allogeneic dendritic cell therapy platform for immuno-oncology and infectious disease, currently in clinical development for the treatment of non-small cell lung cancer and in preclinical development for additional cancers and as a vaccine against infectious diseases, including SARS-CoV-2, the virus which causes COVID-19. For more information, please visit www.lineagecell.com or follow the Company on Twitter @LineageCell.

Forward-Looking Statements

Lineage cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would," "contemplate," project," "target," "tend to," or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to the anticipated completion of patient enrollment in Lineage's Phase 1/2a clinical study of OpRegen. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Lineage's actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including risks and uncertainties inherent in Lineage's business and other risks in Lineage's filings with the Securities and Exchange Commission (the SEC). Lineage's forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. Further information regarding these and other risks is included under the heading "Risk Factors" in Lineage's periodic reports with the SEC, including Lineage's Annual Report on Form 10-K filed with the SEC on March 12, 2020 and its other reports, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Lineage undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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