Lineage Cell Therapeutics Reports Regeneration of Retinal Tissue in Patient Treated With OpRegen RPE Cells for Dry AMD With Geographic Atrophy

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- **First Known Clinical Report of Retinal Tissue Regeneration Following RPE Transplant**
- **Call Scheduled for June 8, 2020 with Therapeutic Area Experts to Discuss Findings**

CARLSBAD, Calif.--(BUSINESS WIRE)--Jun. 1, 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 restoration of retinal tissue was observed in a patient enrolled in a Phase 1/2a study of its lead product candidate, OpRegen®, a retinal pigment epithelium (RPE) cell transplant therapy in development for the treatment of dry age-related macular degeneration (AMD). This 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. Lineage plans to host a live call with two therapeutic area experts Jordi Monés, M.D., Ph.D., Director, Institut de la Màcula and Director, Principal Investigator and Founder, Barcelona Macula Foundation: Research for Vision, and Michael S. Ip, M.D., Chief of Vitreoretinal Surgery Service, Doheny Eye Centers, UCLA, on Monday, June 8, 2020 at 4:30 p.m. ET/1:30 p.m. PT. Drs. Monés and Ip will discuss these data and other results of treatment with OpRegen. Interested parties can access the call on the Events and Presentations section of Lineage's website.

The loss of retina pigmented epithelium (RPE) cells over time creates progressively larger areas of atrophy in the adult retina, leading to impaired vision or complete blindness, a condition known as dry AMD. Humans lack the innate ability to regenerate retinal tissue and replace lost retina cells, which has led to a presumption that progression of geographic atrophy (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. We report 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 and it grew approximately 50% slower than its historical rate during the subsequent six months. These unprecedented 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.

"Any therapy which can save photoreceptors and RPE cells in areas of geographic atrophy would be very important to these patients. It is hypothesized that cells in the transition areas at the boundary of the GA are dysfunctional and dying, but not completely lost," stated Jordi Monés, M.D., Ph.D. "The addition of new RPE cells may restore the microenvironment in surrounding tissue and contribute to the possibility of restoring function to existing cells that otherwise, if left untreated, would inevitably progress to further expansion of the atrophic region."

"Our team has independently reviewed these data as part of our ongoing collaborative efforts with Lineage and I think it is evidence of a partially restorative effect in this patient. We have observed apparent RPE regeneration on detailed review of imaging and will look forward to reviewing additional patient data from the OpRegen clinical trial to determine the reproducibility and durability of this unexpected finding," added Michael Ip, M.D.

"We have evidence at multiple time points which demonstrate a thickening of the outer nuclear layer and restoration of retinal structure. These changes penetrated into the area of GA where those cells are thought to be destroyed and the improvement has persisted over time. The patient also exhibited a consistent seven to ten letter improvement in their visual acuity for the past year. These findings are extremely encouraging and it is important that we investigate why this particular individual experienced a restoration of tissue in the boundary areas of their GA," stated Gary Hogge, Senior Vice President of Clinical and Medical Affairs. "This individual had a multifocal GA and received much greater coverage of cells, either of which may be relevant to these results. Our next steps include seeking to understand the contribution from potentially critical differences in the surgical procedures or baseline characteristics so that we can reproduce this outcome in additional patients."

"To our knowledge, this is the first time any experimental treatment for dry AMD has demonstrated a reduction, rather than expansion, of an area of atrophy over a clinically meaningful time period. If this finding is confirmed in additional patients, I believe it will create a new paradigm for how we and others approach the treatment of dry AMD and will help advance the incredibly promising area of cell therapy in which we enjoy a leadership position, the directed differentiation and transplant of specific cell types to treat severe diseases and conditions," stated Brian M. Culley, Lineage CEO.

OpRegen is currently being evaluated in a Phase 1/2a clinical study in patients with dry AMD with GA. Seventeen of twenty-one expected patients have been enrolled to date. The Company has observed evidence of benefit in some patients, including increases in Best Corrected Visual Acuity (BCVA), reduction in the growth of geographic atrophy 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.

OpRegen was originally developed by Drs. Benjamin Reubinoff, M.D., Ph.D. and Eyal Banin, M.D., Ph.D. of Hadassah University and licensed to Lineage's subsidiary Cell Cure Neurosciences.

KOL Call Information and Webcast

Lineage will host a conference call with Drs. Monés and Ip, on Monday, June 8, 2020 at 4:30 p.m. ET/1:30 p.m. PT to further discuss the results following treatment with OpRegen. A live webcast of the conference call will be available online in the Events and Presentations section of Lineage's website.

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, in clinical development for the treatment of non-small cell lung cancer and preclinical development for additional cancers and 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 potential benefits of OpRegen and Lineage's objectives. 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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