Lineage Cell Therapeutics Presents Additional Interim Data on OpRegen® for Dry AMD With Geographic Atrophy

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- **Seventy-Five Percent of All Cohort 4 Patients Have Experienced BCVA Increases**
- **Visual Acuity Continues to Decline in the Majority of Untreated Eyes**
- **No Acute or Delayed Inflammation or Rejection of OpRegen Observed, Even in Patients Treated with a Reduced Immunosuppressive Regimen**

CARLSBAD, Calif.--(BUSINESS WIRE)--Mar. 23, 2021-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cell transplants for serious medical conditions, today announced new positive interim results from its ongoing, 24-patient Phase 1/2a clinical study of its lead product candidate, OpRegen. OpRegen is an investigational cell therapy consisting of allogeneic retinal pigment epithelium (RPE) cells administered to the subretinal space for the treatment of dry age-related macular degeneration (AMD) with geographic atrophy (GA). Additional interim data were collected on all 24 patients enrolled in the study, including the 12 patients treated in Cohort 4, which feature less advanced disease, better baseline visual acuity, and smaller areas of GA.

Overall, 9/12 (75%) of the Cohort 4 patients' treated eyes were at or above baseline visual acuity at their last assessment, based on per protocol scheduled visits ranging from 3 months to > 2 years post- transplant. Improvements in best corrected visual acuity (BCVA) reached up to +19 letters on an EDTRS chart. In contrast, 9/12 (75%) of the patients' untreated eyes were below baseline entry values at the same time points. Among the newly reported data, three (50%) of the more recently treated Cohort 4 patients have exhibited marked improvements in BCVA ranging from +7 to +16 letters at their last scheduled assessments of at least 4.5 months. Two additional Cohort 4 patients remained within 2 letters of their baseline values (one each above and below). One patient measured 7 letters below baseline.

Previously reported structural improvements in the retina and decreases in drusen density have continued with evidence of durable engraftment of OpRegen cells in some treated patients now extending to more than 5 years in the earliest treated patients. A trend towards slower GA progression in treated compared to fellow eyes also continued, although significant changes in GA growth over a 3-month period following treatment are not expected. Overall, OpRegen has been well tolerated with no unexpected adverse events or serious adverse events.

"Data collected from the six additional Cohort 4 patients which we treated last fall has reinforced our prior results and further supports that treatment with OpRegen may provide clinically meaningful outcomes in dry AMD patients with GA. Improvements in BCVA have become apparent within a few months after dosing, consistent with the predicted activity of an RPE cell transplant," stated Brian M. Culley, Lineage CEO. "If these early indications of a treatment effect are maintained or improve further, it will be another positive indicator for the potential of OpRegen to improve outcomes in this condition. We continue to monitor all patients on study and in the coming months we will be looking in particular for indications of retinal restoration, reductions in the size and growth of the areas of GA, and functional improvement in visual acuity. Further, the multi-year stability of OpRegen transplants, some in excess of 5 years without signs of rejection, is notable for the durability of our allogeneic cell therapy approach, especially as patients did not require long-term immunosuppression."

As part of an ongoing effort to administer the minimally effective dose and duration of immunosuppression, reflecting the COVID pandemic and age of typical AMD patients while ensuring the survival of OpRegen cells, no immunosuppression was utilized beyond the perioperative period of up to 3 months in Cohort 4 patients. Notably, the one OpRegen patient who had received a modified immunosuppressive regimen at baseline which included no tacrolimus and only mycophenolate mofetil, does not show any signs of acute or delayed inflammation or rejection of OpRegen cells. One other patient was diagnosed with COVID shortly after treatment with OpRegen and all immunosuppression was halted and then reinstated once the patient was asymptomatic. This second patient similarly showed no signs of acute or delayed inflammation or rejection of OpRegen cells. Other than the reduced regiments described above, immunosuppressants have been discontinued as scheduled, typically within 90 days post-operatively, and no cases of acute or delayed rejection or inflammation due to OpRegen have been reported.

Additional details regarding this data will be presented as part of a corporate update by Mr. Culley at the Benzinga Global Biotech Small Cap conference on March 24, 2021 at 11:50am Eastern Time / 8:50am Pacific Time. Mr. Culley will also be participating in a panel entitled "Coming Together to Address Unmet Medical Needs," on March 24, 2021 at 12:50pm Eastern Time / 9:50am Pacific Time. Interested investors are encouraged to register for the event in advance: https://www.benzinga.com/events/small-cap/biotech/. The live and archived webcasts from the event will be available on the Events and Presentations section of Lineage's website. Additional videos are available on the Media page of the Lineage website.

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 (vision from 20/65 to 20/250 with smaller 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. Additional objectives include the evaluation of the safety of delivery of OpRegen using the Orbit SDS, manufactured by Gyroscope Therapeutics, Ltd.

OpRegen is a registered trademark of Cell Cure Neurosciences Ltd., a majority-owned subsidiary of Lineage Cell Therapeutics, Inc.

About Dry AMD

Dry age-related macular degeneration (AMD) is a leading cause of adult blindness in the developed world. There are two forms of AMD: wet AMD and dry AMD. Dry AMD is the more common of the two types, accounting for approximately 85-90% of cases. Wet AMD is the less common of the two types, accounting for approximately 10-15% of cases. Global sales of the two leading wet AMD therapies were in excess of $10 billion in 2019. Nearly all cases of wet AMD begin as dry AMD. Dry AMD typically affects both eyes. There are currently no U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) approved treatment options available for patients with dry 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) 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. 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 expected clinical outcomes of dry AMD patients with GA and the expected timing when indications of retinal and reductions in size and expansion of the areas of GA may become apparent. 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 (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 most recent Annual Report on Form 10-K filed with the SEC 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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