



OpRegen® Data Update to Be Featured at 2021 American Academy of Ophthalmology Annual Meeting in Presentation by Michael S. Ip, M.D.

October 26, 2021

CARLSBAD, Calif.--(BUSINESS WIRE)--Oct. 26, 2021-- [Lineage Cell Therapeutics, Inc.](#) (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, reported today that updated interim results from a Phase 1/2a clinical study of its lead product candidate, [OpRegen®](#), an investigational retinal pigment epithelium cell transplant therapy currently in development for the treatment of dry age-related macular degeneration (AMD), will be featured in a presentation at the [2021 American Academy of Ophthalmology \(AAO\) 125th Annual Meeting](#), to be held at the Ernest N. Morial Convention Center, New Orleans, LA (November 12 – 15, 2021). The presentation, “OpRegen Trial: Phase 1/2a Dose Escalation Study of Human Embryonic Stem-Cell Derived Retinal Pigment Epithelium Cells Transplanted Subretinally in Patients with Advanced AMD,” will be presented on November 13, 2021 at 2:38 pm EDT as part of the Gene and Cell-Based Therapies Session, by [Michael S. Ip, M.D.](#), Professor, Department of Ophthalmology at the David Geffen School of Medicine at the University of California - Los Angeles.

In addition to Dr. Ip's presentation, Lineage also intends to announce updated interim results from the Phase 1/2a study next month, which will include a minimum of 12 months of follow-up in all 24 patients treated with OpRegen, including all 12 patients treated in Cohort 4, which had better baseline vision and smaller areas of GA at baseline than earlier cohorts. OpRegen is well-positioned among product candidates in development for dry AMD as the only experimental therapy that has demonstrated an ability to halt or reverse the expansion of geographic atrophy as well as restore layers of retinal tissue in three patients to date. Specifically, outer retinal layer restoration was observed via optical coherence tomography (OCT) and was evidenced by the presence of new areas of retinal pigment epithelium (RPE) monolayer with overlying ellipsoid zone, external limiting membrane, and outer nuclear layer, all of which were not present at the time of baseline assessment. These findings are suggestive of integration of the new RPE cells with functional photoreceptors in areas that previously showed no presence of any of these cells.

The American Academy of Ophthalmology is the world's largest association of eye physicians and surgeons. The mission of the American Academy of Ophthalmology is to protect sight and empower lives by serving as an advocate for patients and the public, leading ophthalmic education, and advancing the profession of ophthalmology. For more information, please visit <https://www.aao.org/> or follow the association on Twitter [@aao_ophth](#).

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 geographic atrophy (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

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 retinal pigmented epithelium, 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](#).

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," "can," "plan," "potential," "predict," "seek," "should," "would," "contemplate," "project," "target," "tend to," "suggest," or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to the projected timing of future announcements or presentations of updated or additional data from the Phase 1/2a clinical study of OpRegen, the potential benefits of treatment with OpRegen in dry AMD patients with GA, the significance of clinical data reported to date from the ongoing Phase 1/2a study of OpRegen, including the findings of retinal tissue restoration, Lineage's plans to meet with the FDA to discuss OpRegen's clinical development, the potential utilization of OCT imaging to measure efficacy in a pivotal clinical trial of OpRegen for the treatment of dry AMD with GA, and the potential for Lineage's investigational allogeneic cell therapies to provide safe and effective treatment for multiple, diverse serious or life threatening conditions. 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 and Quarterly Report on Form 10-Q 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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