OpRegen® (RG6501) 36-Month Visual Acuity Results Featured at Clinical Trials at the Summit 2025

June 23, 2025

- **Mean vision gains of +9 letters among patients with extensive coverage of OpRegen cell therapy to the Geographic Atrophy (GA) lesion site**
- **Evidence of retinal structural improvement persisted out to 3 years**
- **Anatomical and functional improvements occur following a single administration of OpRegen cell therapy**

CARLSBAD, Calif.--(BUSINESS WIRE)--Jun. 23, 2025-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel allogeneic, or "off the shelf", cell therapies for serious neurological and ophthalmic conditions, today announced that 36-month results from patients enrolled in a Phase 1/2a clinical study (ClinicalTrials.gov Identifier: NCT02286089) of RG6501 (OpRegen) in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD), were presented at Clinical Trials at the Summit (CTS) 2025. The presentation, *"OpRegen® Retinal Pigment Epithelium (RPE) Cell Therapy for Patients with Geographic Atrophy (GA): Month 36 Results from the Phase 1/2a Trial,"* was presented by Christopher D. Riemann, M.D., Vitreoretinal Surgeon and Fellowship Director, Cincinnati Eye Institute (CEI) and University of Cincinnati School of Medicine, on behalf of Roche and Genentech, a member of the Roche Group.

"Long term clinical outcomes following a single administration of OpRegen cell therapy is challenging the long-held view that GA causes irreversible damage. A key finding from the Lineage-run phase 1/2a trial was the importance of extensive placement of cells across the area of atrophy. Among patients who received fulsome coverage by OpRegen cell therapy, anatomical and functional benefits from a single administration have lasted for at least three years," stated Brian M. Culley, Lineage CEO. "Over this extended period, improved visual function is not a natural occurrence among patients suffering from GA, making these changes quite promising. Importantly, OpRegen-treated eyes have exhibited mean BCVA scores above baseline at each of the 12-, 24-, and 36-month timepoints, demonstrating consistency as well as durability. In short, patients who received significant coverage of OpRegen cell therapy across their GA are exhibiting long-term outcomes consistent with meaningful disease stabilization and even improvement. We are excited to see any additional insights which our partners, Roche and Genentech, may uncover from the ongoing GAlette study, which is investigating the best way to deliver OpRegen cell therapy to patients with GA secondary to age related macular degeneration (AMD)."

RG6501 (OpRegen) is a suspension of human allogeneic retinal pigment epithelial (RPE) cells currently in development for the treatment of GA secondary to AMD. Subretinal delivery of OpRegen cell therapy has the potential to counteract RPE cell loss in areas of GA lesions by supporting retinal cell health and improving retinal structure and function. It is being developed under an exclusive worldwide collaboration between Lineage, Roche, and Genentech, a member of the Roche Group, and is currently being evaluated in a Phase 2a clinical study, GAlette, in patients with GA secondary to AMD (ClinicalTrials.gov Identifier: NCT05626114).

CTS 2025 Highlights

- Improvement in visual acuity in Cohort 4 patients (less advanced GA than in other cohorts) was present at 12 months (primary endpoint), 24 months, and has now persisted through 36 months
- Gains in Best Corrected Visual Acuity (BCVA) in patients in Cohort 4 (less advanced GA) measured at month 12 remain evident through month 36 following subretinal administration of OpRegen cell therapy
- Mean change in BCVA among treated eyes for patients (n=10) completing 3-year follow up was +6.2 letters (compared to +5.5 letters at 24 months) (Early Treatment Diabetic Retinopathy Study (ETDRS) assessment)
- Improvement in BCVA and outer retinal structure in patients with extensive OpRegen bleb coverage of their GA area was greater than in patients with limited coverage and persisted through month 36
- Effects were greater on average in the five (5) patients with extensive OpRegen cell therapy coverage of atrophic areas at the time of surgical delivery
    - In these patients' treated eyes, the mean change in BCVA was +9.0 ETDRS letters for those completing 3-year follow-up (compared to +7.4 ETDRS letters at 24 months) (n=5)
- Sustained evidence of retinal structural improvement by a quantitative Optical Coherence Tomography (OCT) analysis through 36 months was observed in treated eyes of Cohort 4 patients (less advanced GA than in other cohorts) following a single subretinal administration of OpRegen cell therapy
- At month 36, sustained evidence of retinal structure improvements in external limiting membrane (ELM) and RPE drusen complex (RPEDC) layers on OCT was observed in the subgroup of five patients in Cohort 4 with extensive OpRegen cell therapy bleb coverage of atrophic areas at the time of surgical delivery
    - Mean improvement of RPEDC area compared with baseline was maintained in treated eyes from 24 months (+2.6 mm^2; n=4) to 36 months (+1.9 mm^2; n=5)
        - In comparison, mean change in RPEDC area decreased in untreated fellow eyes from 24 months (-2.8

mm^2; n=4) to 36 months (-3.8 mm^2; n=5)
    - Mean change in ELM area was maintained in treated eyes from 24 months (+0.8 mm^2; n=4) to 36 months (+0.3 mm^2; n=5)
        - In comparison, mean change in ELM area decreased in untreated fellow eyes from 24 months (-1.9 mm^2; n=4) to 36 months (-3.4 mm^2; n=5)

- These data suggest that OpRegen cell therapy may counteract RPE cell dysfunction and loss in GA by providing support to the remaining retinal cells within atrophic areas, and these effects appear durable through at least 36 months after a single administration

- The Phase 2a "GAlette study" evaluating the success of subretinal delivery of OpRegen cell therapy to target areas of GA is currently enrolling (NCT05626114)
    - In addition to evaluating other surgical parameters, this study will test proprietary surgical devices in development for subretinal delivery of OpRegen cell therapy that have potential advantages over currently available devices and procedures

Dr. Riemann's presentation is now available on the Events and Presentations section of Lineage's website.

About Clinical Trials at The Summit (CTS) 2025

Clinical Trials at the Summit (CTS) 2025 brings together a diverse group of experts from around the world to discuss ongoing clinical trials and the latest data, all with the goal of achieving advances in vitreoretinal care. This program will explore the partnerships and strategies required to design and execute effective clinical trials. CTS was founded by Arshad M. Khanani, MD, MA, Director of Clinical Research at Sierra Eye Associates, and is Co-Chaired by Jeffrey S. Heier, MD, Ophthalmic Consultants of Boston and Peter K. Kaiser, MD, Cole Eye Institute, Cleveland Clinic. CTS is an invitation-only, in-person meeting where participants will have the exclusive opportunity to interact with the top national and international key opinion leaders in retina at the Fontainebleau Las Vegas. For more information visit: https://www.ctsretina.org/.

About the OpRegen Phase 1/2a Study

The Phase 1/2a study is an open-label, single-arm, multi-center, dose-escalation trial evaluating a single administration of OpRegen cell therapy delivered subretinally in patients with bilateral GA secondary to AMD. Twenty-four patients were enrolled into 4 cohorts. The first 3 cohorts enrolled only legally blind patients with a best corrected visual acuity (BCVA) of 20/200 or worse. The fourth cohort enrolled 12 patients with impaired vision (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 cell therapy, 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 was to evaluate the safety and tolerability of OpRegen cell therapy as assessed by the incidence and frequency of treatment-emergent adverse events. Secondary objectives include evaluating the preliminary activity of OpRegen cell therapy treatment by assessing the changes in ophthalmological parameters measured by various methods of primary clinical relevance.

About Geographic Atrophy

GA is an advanced form of AMD characterized by severe loss of visual function. GA is a leading cause of adult blindness in the developed world, affecting at least 5 million people globally. There are two forms of advanced AMD: neovascular AMD and GA. GA and neovascular AMD can occur simultaneously in the same eye, and patients treated for neovascular AMD may still go on to develop GA. GA typically affects both eyes.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing allogeneic, or "off the shelf", cell therapies for serious neurological and ophthalmic conditions. Lineage's programs are based on its proprietary cell-based technology platform and associated development and manufacturing capabilities. From this platform, Lineage designs, develops, manufactures, and tests specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. These cells are created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages are transplanted into patients in an effort to replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and to restore or augment the patient's functional activity. Lineage's neuroscience focused pipeline currently includes: (i) OpRegen ®, a retinal pigment epithelial cell therapy in Phase 2a development under a worldwide collaboration with Roche and Genentech, a member of the Roche Group, for the treatment of geographic atrophy secondary to age-related macular degeneration; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of spinal cord injuries; (iii) ReSonance (ANP1), an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; (iv) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage; and (v) RND1, a novel hypoimmune induced pluripotent stem cell line being developed under a gene editing partnership. For more information, please visit www.lineagecell.com or follow the company on X/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. In some cases, forward-looking statements, can be identified by terms such as "believe," "aim," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "can," "plan," "potential," "predict," "seek," "should," "would," "contemplate," "project," "target," "suggest," or the negative version of these words and similar expressions. Such forward-looking statements include, but are not limited to, statements relating to: the potential therapeutic benefits of OpRegen cell therapy in patients with GA secondary to AMD and the significance of the Phase 1/2a clinical study data reported to date. 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, but not limited to, the following risks: that positive findings in early clinical studies of a product candidate

may not be predictive of success in subsequent clinical studies of that candidate; that Roche and Genentech may not successfully advance OpRegen or be successful in completing clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction; that the ongoing Israeli regional conflict may materially and adversely impact our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, all of which are conducted by our subsidiary in Jerusalem, Israel; that Lineage may not be able to manufacture sufficient clinical quantities of its product candidates in accordance with current good manufacturing practice; and those risks and uncertainties inherent in Lineage's business and other risks discussed 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. 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 subsequent reports, which are available on the SEC's website at www.sec.gov. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. Lineage undertakes no obligation to update any forward-looking statement 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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