



## OpRegen® 3 Year Results in Patients With GA Presented at Foundation Fighting Blindness Retinal Innovation Summit 2026

May 4, 2026

- **Gains in best corrected visual acuity (BCVA) of +9 letters at 36 months among patients with extensive coverage of OpRegen cell therapy to the geographic atrophy (GA) lesion site**
- **OCT imaging indicated partial restoration of outer retinal structure, re-appearance of an RPE layer, and features associated with recovery of photoreceptors**
- **Anatomical and functional improvements occur following a single administration of OpRegen cell therapy**

CARLSBAD, Calif.--(BUSINESS WIRE)--May 4, 2026-- [Lineage Cell Therapeutics, Inc.](#) (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing "off the shelf" allogeneic cell therapies for serious medical 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 the [Foundation Fighting Blindness' Retinal Therapeutics Innovation Summit 2026](#). The presentation, "*Retinal Pigment Epithelium (RPE) Cell Therapy in Geographic Atrophy Secondary to Age-related Macular Degeneration: 3 Year Results from the Phase 1/2a Study*," was presented by Eyal Banin, M.D., Ph.D., Center for Retinal and Macular Degenerations, Department of Ophthalmology Hadassah-Hebrew University Medical Center and Faculty of Medicine, on behalf of [Roche](#) and [Genentech](#), a member of the Roche Group.

"We are excited that our partners continue to collect data and highlight positive clinical results from the OpRegen RPE cell therapy phase 1/2a program," stated Brian M. Culley, Lineage CEO. "We remain confident in the potential of OpRegen to address a significant medical need from a single administration, especially because long term clinical outcomes from RPE cell therapy are challenging the long-held view that GA is an irreversible condition, and currently available therapies have not demonstrated a visual benefit. The results presented by Dr. Banin include OCT images which indicate partial restoration of outer retinal structure, including the re-appearance of a retinal pigment epithelial layer as well as features associated with recovery of photoreceptors. It remains notable that among patients who received extensive coverage of OpRegen RPE cells across the area of atrophy (n=5), anatomical and functional benefits have lasted for at least three years, 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 a surgical optimization study intended to assess the best way to deliver OpRegen cell therapy to patients with GA secondary to age related macular degeneration."

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](#)).

### **Retinal Innovation Summit 2026 Highlights**

- Gains in Best Corrected Visual Acuity (BCVA) in patients in Cohort 4 (less advanced GA than in other cohorts) were presented at 12 months (primary endpoint), 24 months, and have now persisted through 36 months following subretinal administration of OpRegen cell therapy
- Mean change in BCVA among treated eyes for Cohort 4 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)
- Effects were greater on average in the five (5) Cohort 4 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 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 complex (RPE-C) layers on OCT was observed in the subgroup of five (5) patients in Cohort 4 with extensive OpRegen cell therapy bleb coverage of atrophic areas at the time of surgical delivery
  - Mean improvement of RPE-C area compared with baseline was maintained in treated eyes from 24 months (+2.6 mm<sup>2</sup>; n=4) to 36 months (+1.9 mm<sup>2</sup>; n=5)
    - In comparison, mean change in RPE-C area decreased in untreated fellow eyes from 24 months (-2.8 mm<sup>2</sup>; n=4) to 36 months (-3.8 mm<sup>2</sup>; n=5)
  - Mean change in ELM area was maintained in treated eyes from 24 months (+0.8 mm<sup>2</sup>; n=4) to 36 months (+0.3 mm<sup>2</sup>; n=5)

- In comparison, mean change in ELM area decreased in untreated fellow eyes from 24 months (-1.9 mm<sup>2</sup>; n=4) to 36 months (-3.4 mm<sup>2</sup>; n=5)
- Imaging evidence of structural benefit and greater gains in visual acuity were seen in study eyes in Cohort 4 patients at month 12, continuing through month 36
- Differences as compared with fellow eyes increased over time, suggesting possible modification of the course of disease
- Quantitative OCT improvements in RPE-C and ELM area and the gains in BCVA were more prominent in patients with extensive compared with limited OpRegen bleb coverage of GA
- Quantitative analysis of OCT imaging revealed areas with partial restoration of outer retinal structure including re-appearance of an RPE layer as well as features associated with recovery of photoreceptors
- These data suggest that OpRegen cell therapy may counteract RPE cell dysfunction and loss in GA by providing support to remaining retinal cells, 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. Banin’s presentation is now available on the [Events and Presentations](#) section of Lineage’s website.

### **About the Retinal Innovation Summit 2026**

The annual Retinal Therapeutics Innovation Summit 2026 is jointly organized by the Foundation Fighting Blindness and the Oregon Health & Science University Casey Eye Institute. Members of the medical and research communities will come together with representatives from the biotech and pharma industries to discuss rapidly emerging ocular therapies and strategize how to remove barriers toward clinical utility for the most advanced retinal disease therapies. The Retinal Therapeutics Innovation Summit features presentations by leading experts on potential therapeutic approaches to treat retinal diseases and how best to deliver them to patients. In this congenial setting, summit attendees discuss progress being made in the field and how to use initial clinical successes to move toward larger scale trials. For more information, visit: <https://www.fightingblindness.org/events/innovation-summit-2026-4761>.

### **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 novel allogeneic, or “off the shelf”, cell therapies for serious medical conditions. Lineage’s programs are based on its proprietary cell-based technology platform, AlloSCOPE™ (Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent Cell Engineering), and associated development and manufacturing capabilities. From this proprietary AlloSCOPE platform, Lineage develops, manufactures, and tests specialized human cells with anatomical and physiological functions similar or substantially 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, and in some instances may be designed to have additional beneficial properties. 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 pipeline currently includes: (i) OpRegen® cell therapy, 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 in preclinical development under a collaboration with William Demant Invest A/S for the potential treatment of auditory neuropathy; (iv) PNC1, a photoreceptor neural cell therapy research initiative being evaluated for development for the potential treatment of vision loss due to photoreceptor dysfunction or damage; (v) RND1, a novel hypoimmune induced pluripotent stem cell line being evaluated for development under a gene editing partnership; (vi) ILT1, a cell therapy research initiative focused on the issue of large-scale production of undifferentiated pluripotent cells, which if successful could be evaluated for the production of islet cells to support a potential treatment of Type 1 Diabetes; and (vii) COR1, a corneal endothelial disease cell therapy in preclinical development for the potential treatment of corneal endothelial disease. For more information, please visit [www.lineagecell.com](http://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," "confident," 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, including the potential to counteract RPE cell dysfunction and cell loss, to restore or improve retinal structure and function from a single administration, to modify the course of the disease, to challenge the view that GA is an irreversible condition, and to address a significant unmet medical need; the significance and predictive value of the Phase 1/2a clinical study data reported to date, including the durability of anatomical and functional improvements observed through 36 months; expectations regarding additional insights that may be uncovered from the ongoing GAlette Phase 2a surgical optimization study, including the assessment of optimal delivery methods for OpRegen cell therapy; and the development and potential advantages of proprietary surgical devices for subretinal delivery of OpRegen cell therapy. 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 clinical data from small patient cohorts, including the Phase 1/2a study, may not be replicated in larger, controlled clinical trials; that Roche and Genentech may not successfully advance OpRegen cell therapy or be successful in completing clinical trials for OpRegen cell therapy and/or obtaining regulatory approval for OpRegen cell therapy in any particular jurisdiction; that the GAlette study may not achieve its objectives, including with respect to surgical optimization and delivery of OpRegen cell therapy; that proprietary surgical devices in development may not demonstrate the anticipated advantages or may not receive regulatory clearance or approval; that the regulatory landscape for cell therapies may change in ways that adversely affect the development, approval, or commercialization of Lineage's product candidates, including changes in FDA or EMA requirements, guidelines, or policies; that competitive therapies for GA or AMD, including currently approved treatments or therapies in development by third parties, may reduce the commercial opportunity for OpRegen or render it less competitive; that market conditions, including changes in reimbursement policies, pricing pressures, or healthcare reform, may adversely affect the commercial viability of Lineage's product candidates; 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, or may experience supply chain disruptions or increased manufacturing costs; that Lineage may require additional capital to fund its operations and may not be able to obtain such capital on acceptable terms, or at all; that Lineage's collaborations with Roche, Genentech, William Demant Invest A/S, and other partners may not continue or may not yield the anticipated benefits; that Lineage's pipeline programs, including OPC1, ReSonance, PNC1, RND1, ILT1, and COR1, may not advance on anticipated timelines or may not demonstrate sufficient safety or efficacy to support further development or regulatory approval; that Lineage may not be able to adequately protect its intellectual property rights or may face challenges from third-party intellectual property claims; that key personnel may depart or Lineage may be unable to attract and retain qualified personnel necessary to execute its business strategy; 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. All forward-looking statements in this press release are made as of the date hereof and are based on information available to Lineage as of such date. 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](http://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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