

From promise to people.

Our mission is to pioneer a new branch of medicine based on the directed differentiation and transplant of allogeneic cells to patients

> CORPORATE PRESENTATION AUGUST 8, 2024 NYSE AMERICAN: LCTX lineagecell.com

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Lineage Cell Therapeutics

#ReplaceAndRestore

Broad Capabilities Cell manufacturing and transplant technology

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Cell types in active development

>200 Cell types for future targeting

Commercial scalability and cell line supply

Highly Differentiated

Allogeneic product candidates

Product candidates in active clinical trials

>50 patients treated with zero cases of rejection

>\$1B

Addressing multi-billion dollar markets

Validated Technology

Global partnership for lead asset OpRegen®

> \$670M³ Partnership Genentech A Member of the Roche Group

D Unprecedented cases of retinal regeneration

Single administration per patient

* Includes \$50M up front payment received Jan 2022, \$620M of eligible milestones, plus double-digit royalties on sales 3

Neuroscience Cell Therapy Pipeline – 100% Allogeneic



Lineage Technology: Two-Step Allogeneic Cell Production



- Pluripotent stem cell lines (PSCs) provide an <u>endless supply</u> of undifferentiated starting material for all programs
- PSCs can become each of the 200+ cell types of the human body
- No genetic editing is required

- The target cell has been validated by evolution
- Residual pluripotent cells are undetectable
- Generates IP (~375 issued and pending patents)
- Ready to inject formulation (no dose preparation delay)
- One-time treatment cells integrate without rejection
- Scalable process for clinical and commercial use

Requirements for a Successful Cell Therapy

Control (Safety) & Reproducibility

- Source line characterization, cell banking, versatile expansion systems
- Differentiation process development; culture conditions, optimization
- Analytical methods, in-process controls, release criteria

Lineage's Internal cGMP Facility

Multiple Clean Rooms for Parallel cGMP Production Runs; Staff of >50



Purity / Identity

- Clinically compatible post-production processing
- Analytical method development for process control and product release



Potency

- Functionality and performance testing, reflecting MOA
- Enhancements; genetic modification (optional), various expression systems



Scalability

- Scale-up modalities, substrates, harvesting protocols
- Clinical and commercial throughputs for drug process and product
- Commercially-attractive cost of goods





OpRegen® RPE Cell Transplants to Treat Dry AMD

Improving structure and function

Worldwide Collaboration for OpRegen (RG6501)

- Allogeneic retinal pigment epithelial (RPE) cell transplant to treat ocular disorders (dry AMD with GA)
- Genentech funds development and commercialization
- \$50M up front received; eligible for \$620M of milestone payments plus double-digit royalties

125 YEARS Celebrate Life

"The moment our goal shifted from preservation to restoration"

Roche

"Our recent partnership with Lineage Cell Therapeutics...is one of the important routes we are pursuing....The hope is that this treatment could not only slow down progression of the dry form of AMD, <u>but also restore function to the</u> retina."



Cell therapy is a powerful approach for turning cells into living medicines

"Cell-based therapies provide the possibility to replace dying or damaged eye cells with new healthy ones. Our aim is to repair the underlying cellular structure of the retina – a thin layer of tissue that lines the back of the eye – to preserve and even restore vision."

-Tom Zioncheck, Roche

Genentech

A Member of the Roche Group

New OpRegen Agreement Announced May 2024

- Reflects an additional commitment by Genentech for the benefit of the OpRegen program
- Lineage to provide clinical, technical, training and manufacturing services which further support the ongoing advancement and optimization of the OpRegen program
- Additional services **fully funded** by Genentech and will include:
 - Activities to support ongoing Phase 1/2a clinical study
 - Activities to support currently-enrolling Phase 2a clinical study
 - Additional technical training and materials related to Lineage's cell therapy technology platform to support commercial manufacturing strategies



Millions Suffer from Vision Loss due to Dry-AMD

- Age-related macular degeneration (AMD) presents in two forms, wet and dry
- Wet age-related macular degeneration (wet AMD) is usually caused by blood vessels that leak fluid or blood into the macula
- **Dry** age-related macular degeneration (dry AMD) involves the loss of retinal pigmented epithelium (RPE cells), creating an area of geographic atrophy (GA), causing impaired vision and blindness
- Wet AMD supports >\$10Bn¹ in product sales, and dry AMD is eight times more common²



Image courtesy of Macular Society

Lineage Approach - OpRegen, a "Complete" Approach

OpRegen is a one-time injection of fully mature and functional RPE cells intended to: 1) replace and restore retinal tissue (anatomy), and 2) preserve or improve vision (function)



Phase 1/2a Trial Complete, Long-Term Follow-Up Ongoing





Generally well-tolerated, no reports of rejection

Cohorts 1-3 (n=12): 12-month gains in visual acuity averaged <5 letters



Cohort 4 (Initial Efficacy) 12 Impaired Vision Patients



Patients with extensive coverage of atrophic area and foveal center (n=5): 12-month gains in visual acuity averaged +12.8 letters

Cohort 4 (n=10): 24-month gains in visual acuity averaged +5.5 letters



All patients (n=5) with extensive coverage of their area of atrophy with the OpRegen surgical bleb showed evidence of retinal structure improvement

Exploratory Objective: Onset of Structural Improvement In Study Eyes with Extensive OpRegen Bleb Coverage (n=5)

<u>Structural improvement</u> was assessed by 3 independent expert reviewers and based on meeting all of the following pre-specified criteria^a:

- a. Reduction in outer plexiform layer and/or inner nuclear layer subsidence
- b.Reappearance of external limiting membrane
- c. Increased hyperreflectivity of RPE and/or Bruch's membrane or reduction of hypertransmission

Cases were assessed to have structural improvement if determined by at least 2 of the 3 reviewers

^a On at least two non-adjacent B scans; the onset of improvement may be confounded by surgical bleb resolution.

Follow-up mode was turned on during acquisition of these OCT scans to enforce longitudinal registration. Registration was verified manually by comparing choroidal patterns. There may be slight offset of inner retina blood vessels due to eye orientation difference during acquisition.



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Cohort 4 (Less advanced GA) BCVA Gains in Study Eyes Sustained 24 Months Post Treatment



Quantitation of RPEDC and ELM Area Shows Cases of Improvement Between Baseline and 24 Months Post Treatment



ELM, external limiting membrane; RPEDC, retinal pigment epithelium drusen complex.

^aSegmentation result is generated by Genentech EyeNotate OCT segmentation algorithm, reviewed and corrected by a single masked expert grader. ^bELM map, binary external limiting membrane presence/absence map, green when ELM is present, dark blue when ELM is absent.

Case #14

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Maintenance or Improvement of RPEDC Observed in Patients with Extensive OpRegen Bleb Coverage of GA



Thick lines represent the mean and error bars represent standard error. Data cutoff: 30 Oct 2023.

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Maintenance or Improvement of ELM Observed in Patients with Extensive OpRegen Bleb Coverage of GA



Thick lines represent the mean and error bars represent standard error. Data cutoff: 30 Oct 2023.

Preliminary Evidence of Maintenance of Structural Improvement 24 Months Post-Treatment: A Case Study (Case #14)



CFP, color fundus photography; cRORA, complete RPE and outer retinal atrophy; RPEDC, retinal pigment epithelium drusen complex ^aELM map, binary external limiting membrane presence/absence map, green when ELM is present, dark blue when ELM is absent RPEDC and ELM maps are generated by Genentech EyeNotate OCT segmentation algorithm; the segmentation results are reviewed and corrected by a single masked expert grader.

Long-Term Vision Preservation in Study Eye: A Case Study (Case #14) Vision Loss from GA Progression Over Time in Fellow Untreated Eye



Onset of Structural Improvement Within 3 Months in All 5 Patients with Extensive Bleb Coverage



- Structural improvement was only observed within GA lesions covered by surgical bleb
- Maintenance and/or greater structural improvements were observed over time
- These patients also had an average +4.4 letter BCVA gain at Month 3, and +12.8 letter BCVA gain at Month 12

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Greater Visual and Structural Improvements in 5 Patients in Cohort 4 with Extensive Bleb Coverage

Bleb Coverage

Minimal to no bleb

coverage of GA area

(n=7)



BCVA Change in Study Eye at Month 12 Mean Book and the service of the service of

RPE and ELM Change in Study Eye at Month 12



Extensive Bleb Coverage Considerable bleb coverage of GA area (including fovea) (n=5)

> ELM, external limiting membrane Error bars represent standard error Data cutoff: 18 Jan 2022

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Safety Summary¹ OpRegen Was Well Tolerated With an Acceptable Safety Profile

- All 24 (100%) treated patients reported ≥1 AE and ≥1 ocular AE
 - Most frequent systemic AE: URTI (n=7)
 - Most frequent ocular AEs: conjunctival hemorrhage/hyperemia (n=17) and ERM (n=16)
 - The majority of AEs reported (Cohorts 1-3, 87%; Cohort 4, 93%) were mild
 - No cluster of AEs related to immunosuppressive regimen were reported
 - One patient discontinued due to an AE (stage IV lung adenocarcinoma unrelated to treatment)
- No cases of rejection have been reported
- No acute or delayed intraocular inflammation, or sustained intraocular pressure increase observed

¹Ho A, et al. Presented at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. Denver CO, USA. May 1-4, 2022. ERM, epiretinal membrane; URTI, upper respiratory tract infection. Data cutoff: 18 Jan 2022

Ongoing Development: Phase 2a Trial



A multicenter, open-label, single arm clinical study in patients with geographic atrophy (GA), secondary to age-related macular degeneration

- Study managed and funded by Genentech
- Seeks to evaluate the success and safety of subretinal delivery as well as preliminary activity of OpRegen
- Estimated enrollment up to 60 patients
- Primary objectives:
 - Proportion of patients with subretinal surgical delivery of OpRegen to target regions, and
 - Incidence and severity of procedure-related adverse events at 3 months following surgery
- Secondary objective:
 - Proportion of patients with qualitative improvement in retinal structure, determined by SD-OCT

Currently enrolling at 6 study sites in U.S. & Israel

(ClinicalTrials.gov: NCT05626114)

OpRegen - A Multi Billion-Dollar Opportunity

- All patients (n=5) with extensive coverage of their area of atrophy with the OpRegen surgical bleb showed evidence of retinal structure improvement
- Market opportunity **not limited** by monogenic deficiencies (e.g., gene therapy)
- Well-tolerated; no cases of rejection (90d immunosuppression)
- Phase 1/2a study Cohort 4 patients who exhibited average visual acuity gains of 7.6 letters after 12-months, remained above baseline after 24 months (+5.5 letters);
- Mean BCVA gains at 24 months greater among 5 patients with extensive surgical bleb coverage of GA lesion than those with no or limited bleb coverage (+7.4 letters); greater BCVA gains were associated with evidence of anatomical improvement in outer retinal structure.
- Potential application in **additional retinal diseases** (example: Stargardt disease)
- **Issued** patents cover aspects of production, characterization, and formulation
- Fast Track designation from FDA
- Validating development partnership with global ophthalmology leader, Genentech
 - New services agreement established May 2024 to support ongoing development



Key Takeaway for the Lineage Approach

In certain settings, replacing whole cells may provide restorative benefits beyond the reach of traditional approaches

#replaceandrestore

Repeating Success – OpRegen as a Case Study and Guide



Control (Safety) & Reproducibility

- · Multiple clinical batches generated and released
- Comparability testing performed on batches
- Single source, master bank cell line
- No reports of transplant rejection



Characteristics of a Commercially-Successful Cell Therapy Product



Purity/Identity

- Highly pure RPE via flow cytometry
- Multiple identity markers utilized
- No residual PSCs detectable

Potency/Functionality

- Phagocytosis assay
- Trans-epithelial resistance (polarization)
- Differential apical and basal growth factor secretion



Scalability

- Dynamic culturing system (3D, not 2D)
- Bioreactor and microcarriers for expansion and scale-up
- More than 2500 treatment courses per 3L batch









OPC1

Oligodendrocyte Cell Transplants for Spinal Cord Injuries

30 patients treated to date

Spinal Cord Injury (SCI) Burden & Unmet Needs

- Approx. 18,000 cases per year (US)¹
- A significant burden for patients and caregivers²
 - 67% of patients are unemployed 10 years post-injury
 - Lifetime healthcare costs can reach \$5M for one patient
- Lifelong impairment
- Most common in ages 16-30



- Primary feature of a SCI is loss of mobility
- Goal of OPC1 therapy is to restore arm, hand, and finger function
- Greater mobility increases independence and quality of life
- Gains in motor function, particularly in the upper extremities, can provide significant benefits in self-care and lower costs of care



Oligodendrocyte Cells as a Treatment Option for SCI

Transplanting oligodendrocytes may provide additional motor function and improve quality of life

- Oligodendrocyte progenitor cells (OPCs) are precursors to the myelinating cells of the central nervous system
- Myelinating cells provide insulation to nerve axons in the form of a myelin sheath
- Myelin is essential for proper function of neurons



- OPC1 is generated from an NIH-registered cell line
- Cells are allogeneic ("off the shelf") and not taken from the patient
- **OPC1 is a one-time injection** into the spinal cord
 - Subacute dosing occurs 3-6 weeks post-injury, providing time for consent and transportation
- Immunosuppression is brief (60 days)
- Cells are cryopreserved in a ready to use, thaw-and-inject formulation



OPC1 Triple Mechanisms of Action

Preventing Cavitation



Myelination of Axons

Neurotrophic Factors





Expected Recovery¹ vs OPC1: Motor Function Gains



1. Steeves JD, Lammertse DP, Kramer JL, Kleitman N, Kalsi-Ryan S, Jones L, Curt A, Blight AR, Anderson KD. Outcome Measures for Acute/Subacute Cervical Sensorimotor Complete (AIS-A) Spinal Cord Injury During a Phase 2 Clinical Trial. Top Spinal Cord Inj Rehabil. 2012 Winter;18(1):1-14. doi: 10.1310/sci1801-1. Epub 2012 Jan 31. PMID: 23239927; PMCID: PMC3519288.

2. Fessler, R. G., Ehsanian, R., Liu, C. Y., Steinberg, G. K., Jones, L., Lebkowski, J. S., Wirth, E. D., III, & McKenna, S. L. (2022). A phase 1/2a dose-escalation study of oligodendrocyte progenitor cells in individuals with subacute cervical spinal cord injury, Journal of Neurosurgery: Spine (published online ahead of print 2022). Retrieved Aug 19, 2022, from https://thejns.org/spine/view/journals/j-neurosurg-spine/aop/article-10.3171-2022.5.SPINE22167/article-10.3171-2022.5.SPINE22167.xml

Real-World Impacts from Motor Level Improvements

Motor level gains translate into meaningful improvements in self-care and large reductions in costs of care



Activities of Daily Living across different levels of motor function after cervical complete SCI. Modified from Whiteneck et al. 1999)

OPC1 Cervical Clinical Trial - Adverse Events

The majority of adverse events were mild to moderate in severity

All Treated Subjects (N=25)	AEs	SAEs
Total	534	29
Related to OPC1	1*	0
Related to Injection Procedure	20	1
Related to Tacrolimus	11	1

To date, there have been <u>no</u> serious adverse events related to the OPC1 cells Safety data is available for 2 to 5 years on all 25 patients

*One AE possibly related to OPC1 was a Grade 2 dysesthesia that began 47 days post-injection but had resolved by the Year 2 follow-up visit

OPC1 Cervical Clinical Trial - Cell Engraftment

12- and 24-Month MRI Scans Indicate Durable Engraftment

- Cystic cavitation (syringomyelia) is a disorder which can damage nerve fibers and is expected to occur in ~80% of matched SCI cases
- MRIs show formation of a tissue matrix at the injury site, indicating OPC1 cells have durably engrafted to help prevent syringomyelia
- 96% (24/25) of OPC1 patients had serial MRI scans that indicated no sign of a lesion cavity at 24 months (for 22 available scans)



Weighted sagittal MRI

OPC1 Thoracic & Cervical Clinical Trials Overview

- Thoracic phase 1 clinical trial (N=5)
 - All subjects followed for at least 10 years (Journal of Neurosurgery Spine, Vol 37, Issue 3, 2022)
 - No unexpected serious adverse events attributable to the OPC1 transplant:
 - -No evidence of neurological decline
 - -No enlarging masses
 - -No further spinal cord damage
 - -No syrinx formation
- Cervical phase 1/2a clinical trial (N=25)
 - All subjects evaluated for at least 2 years (Journal of Neurosurgery Spine, Vol 37, Issue 6, 2022)
 - No unexpected serious adverse events related to the OPC1 transplant;
 - No enrolled patients had worsening of neurological function;
 - Durable motor improvements:
 - -4 of 6 subjects gained at least 2 motor levels of improvement on at least one side at 12 months (cohort 2)
 - -5 of 6 subjects gained at least 2 motor levels of improvement on at least one side at 24 months (cohort 2)
 - -1 subject achieved 3 motor levels of improvement on one side; maintained at 3 years (cohort 2)

OPC1 Manufacturing Improvements: Lower Impurities



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OPC1 Single-Cell RNA-Seq (scRNA-seq) Data



The Lineage-improved process is reproducible, 10X original scale, is comparable *in vivo* to the original material, but is devoid of non-targeted (i.e. epithelial) populations

Novel Spinal Cord Delivery System

- Manual Parenchymal Spinal Delivery System
 - Designed to be easier to use and safer for patients

Enhanced safety

- Attaches directly to the patient, compatible with breathing motion
- Designed to administer OPC1 without stopping patient ventilation

• Improved user experience:

- Smaller and fewer components
- Single hand operation
- Better stability and control

Compatible with Lineage's new thaw and inject formulation

- 5 minutes from frozen to ready for administration
- Eliminates ~90% of dose prep compared to prior clinical material





- Open label, multi-center, device safety study in 3-5 subacute and <u>for the first time</u>, 3-5 chronic injury patients
 - Complete (ASIA-A) or incomplete (ASIA-B) SCI of cervical (C4-C7) or thoracic (T1-T10) vertebrae
- Initial clinical site opening expected as soon as feasible, pending FDA feedback
- Primary objective
 - Evaluating the **safety** of a novel device to deliver OPC1 to the spinal parenchyma
- Primary endpoint
 - Safety, measured by adverse events (AEs) through 30 days post-injection
- Secondary endpoints
 - Safety and tolerability through 90 days post-injection

Exploratory endpoints

- Potential improvements in neurological impairment, function, and pain

OPC1 Program Summary

Key Takeaways

- Unmatched experience one of the longest running trials in the field and first of its kind
- Indication of efficacy compared to best available matched control
- Excellent overall safety profile
 - 5 years follow up in cervical SCI
 - 10 years follow up in thoracic SCI
- Higher purity and production scale has been achieved
- Learnings can be applied to next trial
 - Inadequate decompression was associated with the two worst outcomes

Next Steps

- DOSED study to evaluate safety of new delivery system (N= 6-10)
 - 3-5 subacute and for the first time, 3-5 chronic injury patients
- Preparations underway for larger, controlled clinical trial
 - Engaging with patients, patient advocacy organizations, and other experts
 - Assessing clinically-meaningful endpoints
- Eligible for grants from
 - California Institute of Regenerative Medicine (CIRM)
 - Department of Defense

OPC1 Asset Overview

- OPC1 utilizes targeted cell replacement (similar to RPE for dry AMD)
- OPC1 has RMAT & Orphan Drug Designations
- OPC1 has received >\$14M in grant support from CIRM
- OPC1 may have application in other demyelinating conditions



"There's no reason to not look forward in the same way now that I had before all of this happened. I'm looking forward to driving again... it's a bright future."

- Lucas Lindner, OPC1 Patient



"I couldn't drink, couldn't feed myself, couldn't text or pretty much do anything, I was basically just existing. I wasn't living my life, I was existing."

- Kris Boesen, OPC1 Patient



"My recovery from the point of the trial until now has been immense. A lot more than I would have expected. So, if I had the chance to go back and do it again, I 100% would."

- Jake Javier, OPC1 Patient



"My AIS score improved from an AIS-A over to an AIS-B, because I've got a lot of feeling under my injury level that I didn't have right when I broke my neck. And I would attribute those directly to spinal cord injury cells."

- Chris Block, OPC1 Patient





ANP1, PNC1 and RND1

Looking Ahead: Preclinical and Research Programs

Preclinical Cell Transplant Programs



ANP1 Auditory neuron progenitor cells

- Intended to treat auditory neuropathy spectrum disorders (hearing loss)
 - Hearing loss afflicts >400 million people worldwide
- IP filed covering composition and methods of generating ANPs
- Positive initial proof of concept results
 - Initial results demonstrated delivery, engraftment, and survival of ANP1 cells into specific target areas
 - Results support advancement of the ANP1 program into functional preclinical testing
- Progressed from product concept to pre-clinical testing in <12 months and less than \$1M

ANP1 for Hearing Loss

- First in class cell therapy to replace damaged parts of the inner ear and restore hearing
 - First internally-generated development program
 - Auditory neuronal transplants with initial focus on treatment of auditory neuropathy spectrum disorders
 - Replacing auditory neurons or augmenting damaged auditory neuron population may provide benefits beyond the reach of alternate gene therapy and small molecule approaches that target a single pathway
- Proprietary and protected manufacturing process based on in-house manufacturing expertise
 - Leverages corporate strength rapidly translating R&D processes to GMP to facilitate IND submission
 - Product will utilize Lineage's proprietary Thaw and Inject formulation which provides ease of administration to target physicians
- Compelling results generated in preliminary in vitro and in vivo preclinical studies
- Patent applications covering composition and methods for generating ANP's
 - Filed IP includes methods of treatment that employ these cells for treatment of auditory neuropathy



ANP1 Preclinical Results

- Delivery, engraftment and survival of ANP1 in preclinical models through collaboration with Dr. Yehoash Raphael and University of Michigan
- Comparison of multiple models of chemical deafness and routes of administration
 - Neomycin vs ouabain induced deafness
 - Modiolus vs scala tympani administration
- Conclusions
 - ANP1 cells observed up to 7 days postadministration
 - Ouabain model exhibited fewer side effects, improved depletion of endogenous neurons, with ANP1 engraftment throughout a larger area
 - Both routes of administration appeared effective
- Planned next steps are functional preclinical models of hearing loss with ANP1



ANP1 cells (labeled red) observed up to 7 days after administration

Research Cell Transplant Programs

PN Pho

PNC1

Photoreceptor cells (rods and cones)

- Intended to treat conditions of photoreceptor loss or dysfunction
- Leverages knowhow and capabilities in ophthalmology
- IP filed covering compositions and methods of generating PRs



RND1 Undisclosed Indications

- Augments experience with engineering desirable properties into cell lines
- mRNA-based gene editing (knock-in, knock-out)
- B2M-deletion and HLA-E over-expressing "hypoimmune" pluripotent cell line
- Cell line intended to support creation of product candidates for the treatment of central nervous system (CNS) disorders and other neurology indications

Staged Investment - Preparing for Future Success

Option and License Agreement:

- -Expands range of core technology
- —Collaboration provides an opportunity to add capabilities in 3 new areas:
 - -Ex-vivo gene editing, hypo immunity, induced pluripotent stem cells (iPSCs)
- -Offers potential to expand into new disease areas
- -Option structure de-risks assets prior to larger financial commitments
- -Augments experience with engineering desirable properties into cell lines

eterna

Lineage Corporate Profile



Corporate Headquarters Carlsbad, California



Research & Development Carlsbad, California



Manufacturing Jerusalem BioPark, Israel

Strong Financial Position

\$38.5M

Cash & equivalents at 6/30/2024

Market Capitalization

~\$167M*

Employees

75* (U.S. & Israel)

50



Our Inspiration.

View their stories at lineagecell.com/media

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