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NYSE American: LCTX

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Lineage Cell Therapeutics

Lineage is a leading cell therapy company which manufactures and transplants specific types of cells to treat injuries and disease

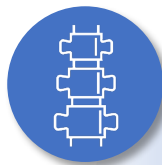
Three Clinical-Stage Programs



OpRegen®

for Dry Age-Related
Macular Degeneration
with GA (Dry AMD)

Phase 1/2



OPC1

for Spinal Cord Injury
(SCI)

Phase 1/2



VAC2

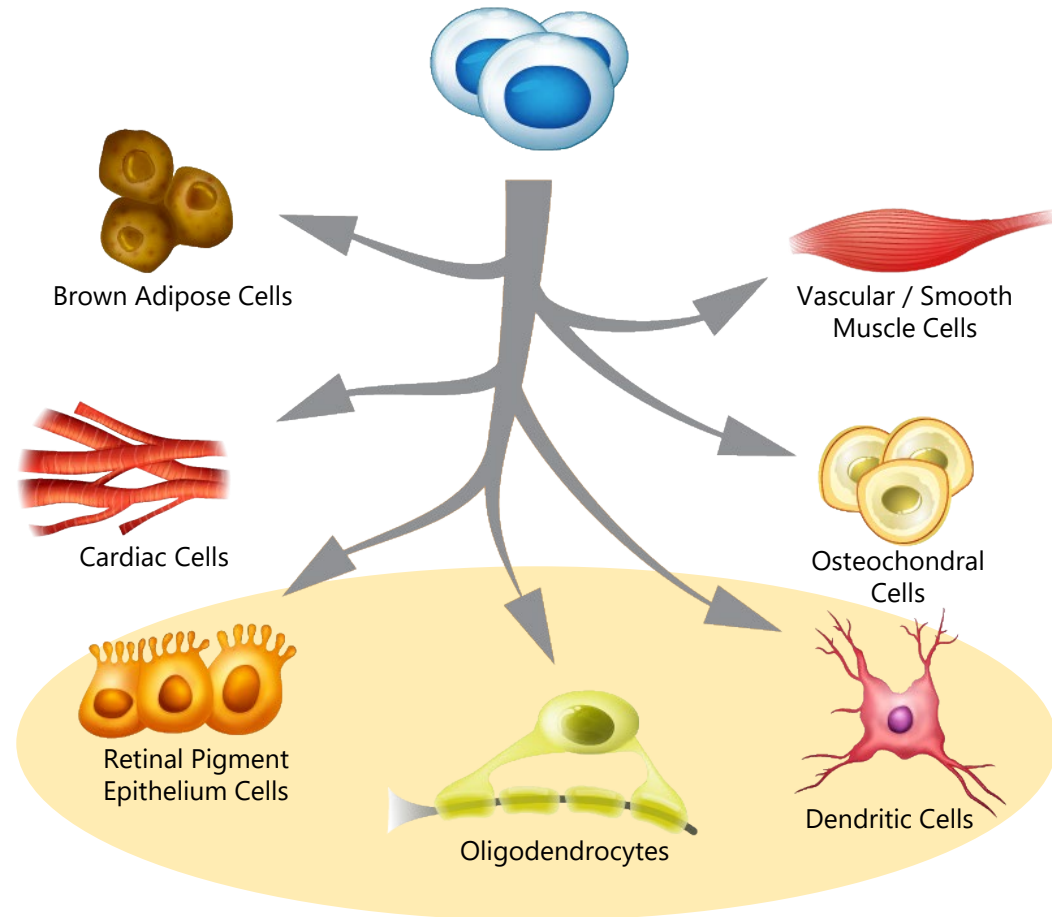
for Oncology
(Non-Small Cell Lung
Cancer, NSCLC)

Phase 1

~850 cell therapy-related patents and pending applications worldwide

Cell Therapy Platform Technology

- The Lineage Platform starts with normal human cell lines, which avoids risks from genetic modifications
- These cells have the capacity to become any human cell type, offering many potential indications
- A cell's lineage is controlled to generate only the desired cell type
- The cells have high proliferative capacity and can produce abundant clinical material



CURRENT CLINICAL PROGRAMS

Clinical-Stage Pipeline and Partners

Cell Therapy Programs	Phase I	Phase II	Partnerships & External Funding
OpRegen® Dry Age-Related Macular Degeneration with GA (Dry AMD)			 רשות החדשנות Israel Innovation Authority \$16M
OPC1 Spinal Cord Injury (SCI)			 CALIFORNIA STEM CELL AGENCY >\$14M
VAC2 Non-Small Cell Lung Cancer (NSCLC)			 CANCER RESEARCH UK >\$10M in-kind



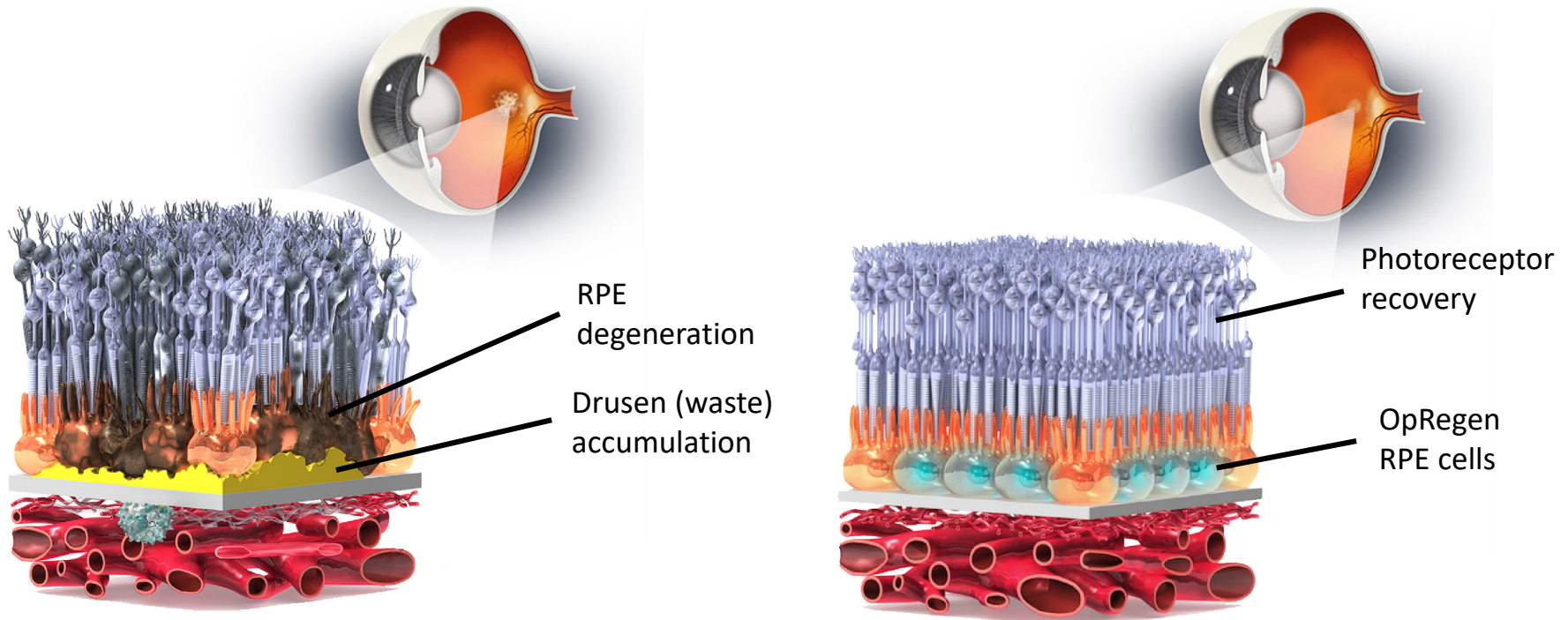
Cell Therapy for Dry AMD

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Dry Age-Related Macular Degeneration (AMD)

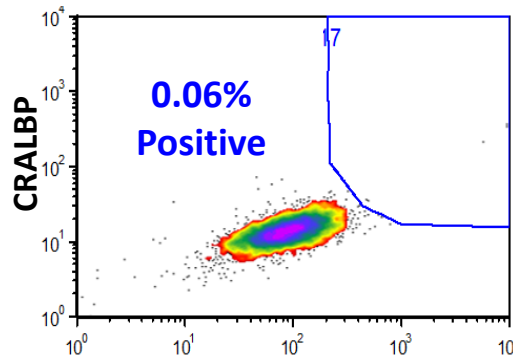
- Dry-AMD involves the loss of specialized retina cells (RPE), causing impaired vision
- OpRegen is a suspension of RPE cells, manufactured from a cell line and injected in the sub-retinal space



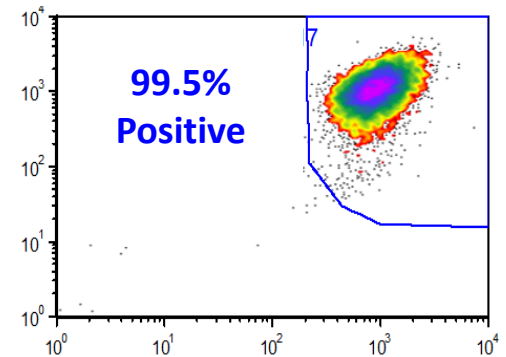
In-House GMP Manufacturing of RPE Cells

The lineage of an established line of pluripotent cells can be controlled to create a population of substantially pure RPE cells

**Identity Assay
(purity)**

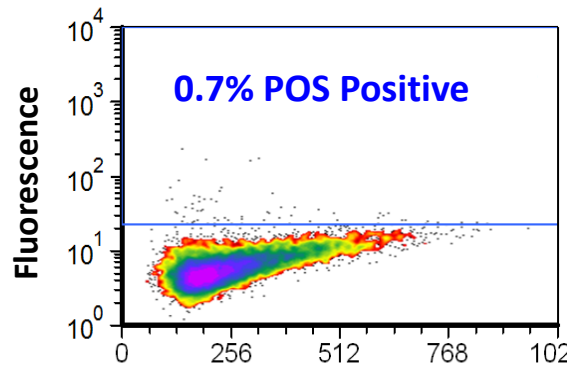


Undifferentiated cells

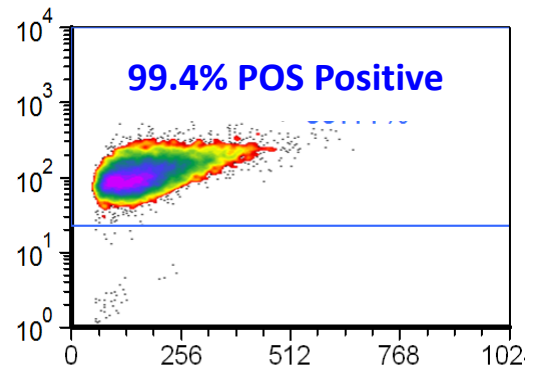


OpRegen RPE cells

**Functional Assay
(phagocytosis)**



Undifferentiated cells



OpRegen RPE cells

In-House GMP Production

Extensive experience directing the lineage of pluripotent cells into terminally-differentiated, specific cell types (such as retina cells, glial cells, etc.)

- **Cell banking and handling**
- **Process development**
- **Manufacture of clinical material**
- **Scale-up into multi-liter bioreactors**
- **Multiple clean rooms for parallel GMP production runs**

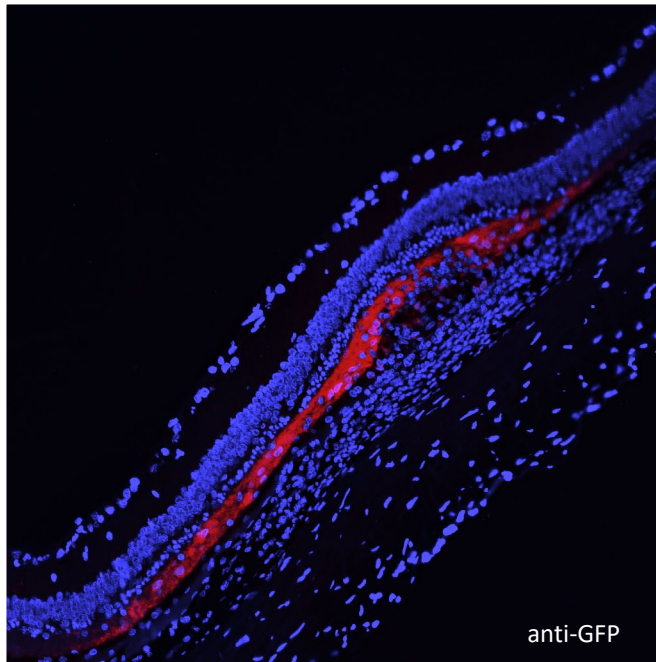


Engraftment and Survival of RPE Cells

- OpRegen cells were counter-stained with DAPI (red line)
- OpRegen cells form a sustained monolayer in multiple species

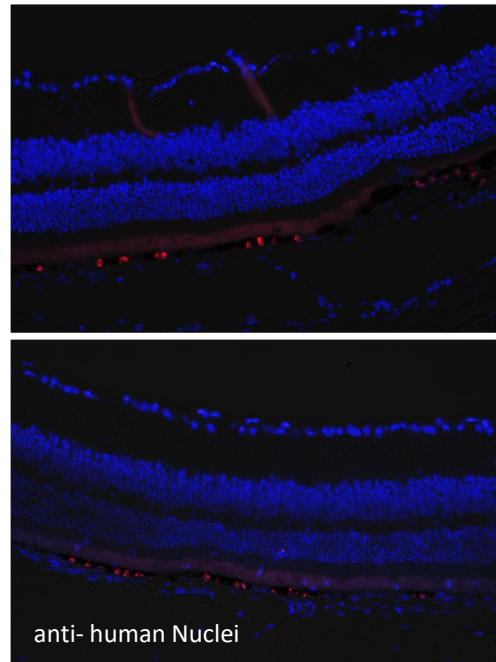
RCS Rat

19 weeks post transplantation



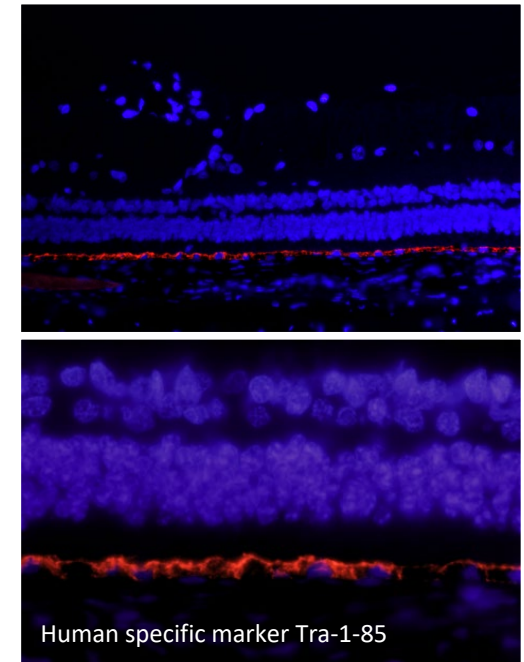
NOD-SCID Mouse

2 months post transplantation



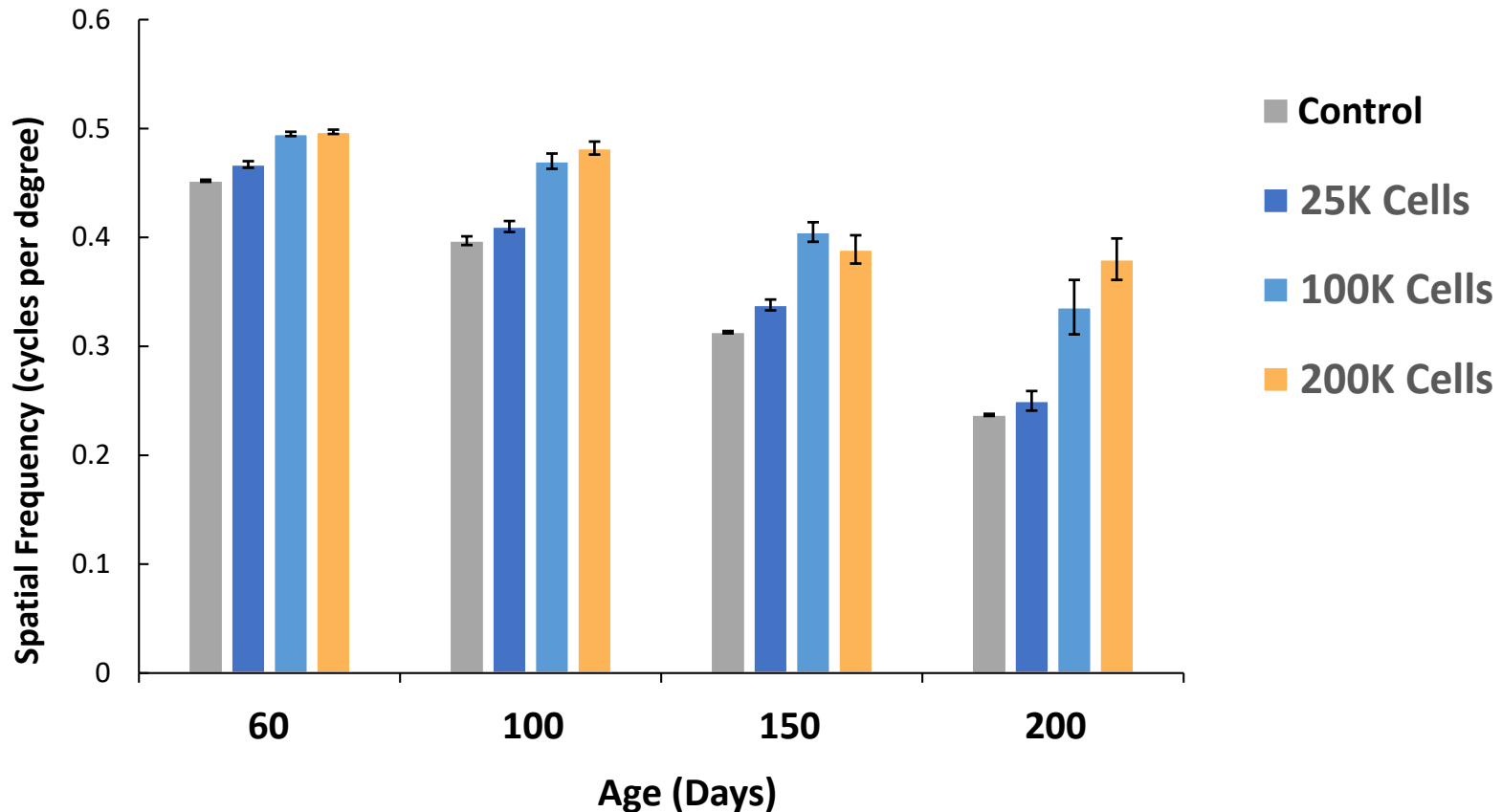
Pig

2 months post transplantation



Improved Visual Acuity in RCS Rat Model

Dose-dependent rescue of vision can be observed via optokinetic nystagmus



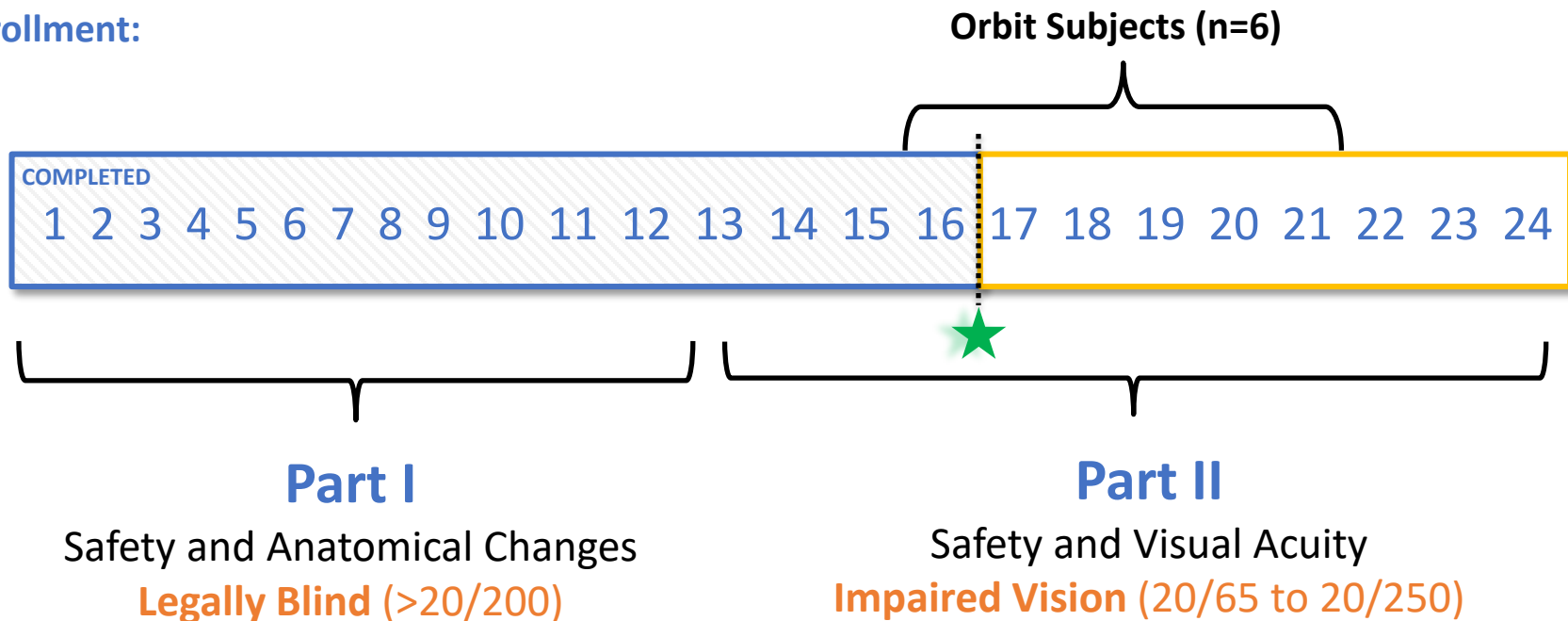
Ongoing Phase I/IIa Clinical Trial

Purpose: To evaluate the safety and efficacy of sub-retinally transplanted RPE cells in patients with advanced dry AMD with geographic atrophy

Design: Open label, single-arm, and multi-center (US and Israel)

Dose and Administration: One 50ul dose of cells injected into the subretinal space

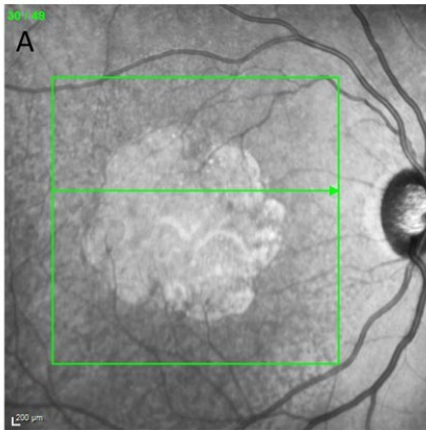
Enrollment:



Phase 1/2a Patient Data: Cell Engraftment

Stable engraftment of OpRegen RPE cells in a human subject

Baseline



A large region of geographic atrophy is present (lighter circular area)

Month 4

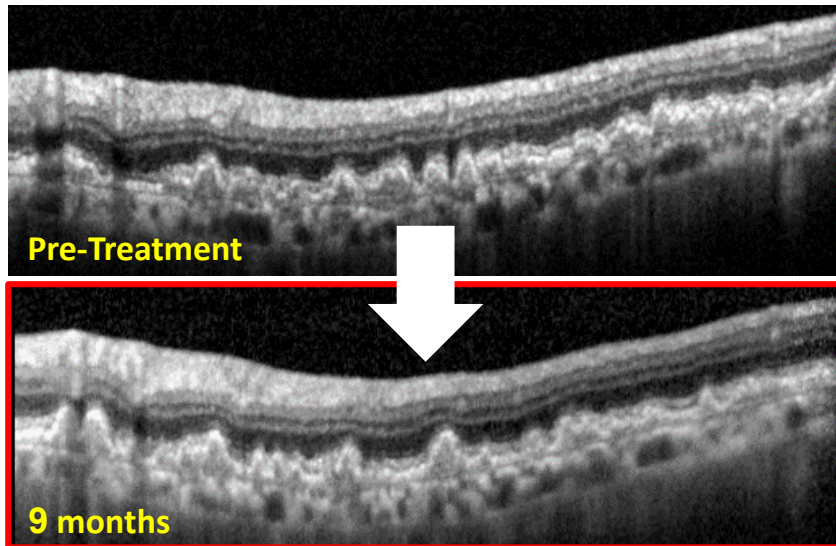


In areas of cell administration (upper green box), pigmentation is similar to normal retinal appearance, suggesting successful engraftment of cells

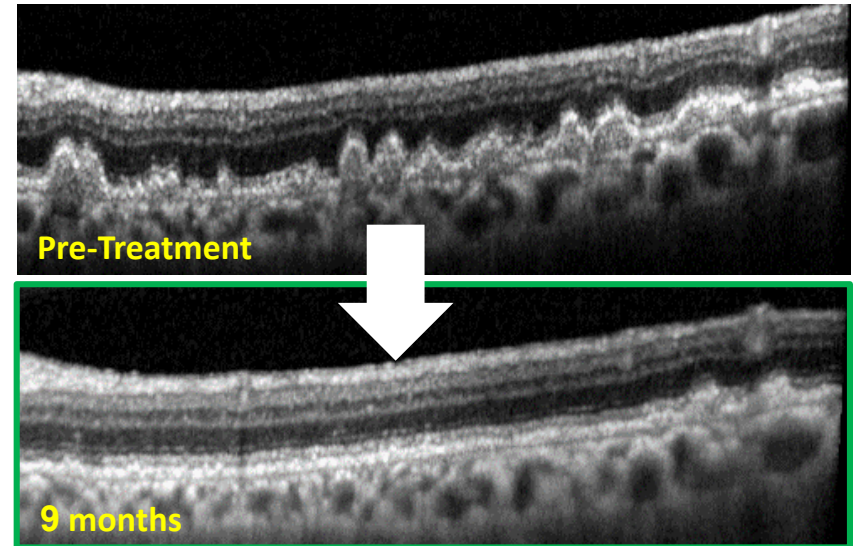
Phase 1/2a Patient Data: Drusen Reduction

- Drusen accumulation is observed at pre-treatment (wrinkled white line)
- A reduction or change to drusen is observed through month 9 in some patients

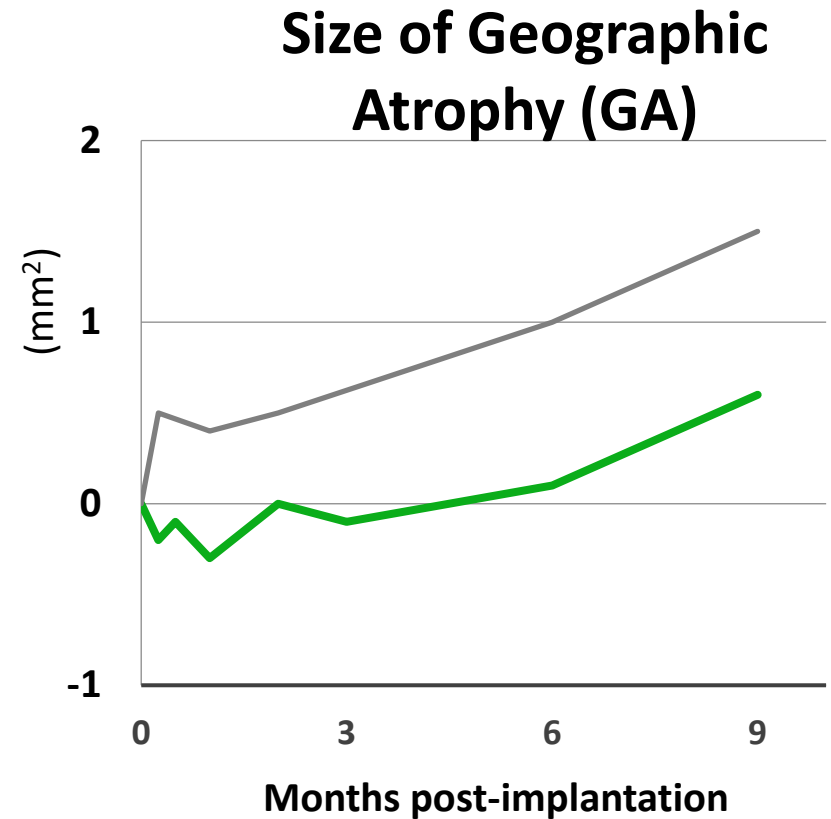
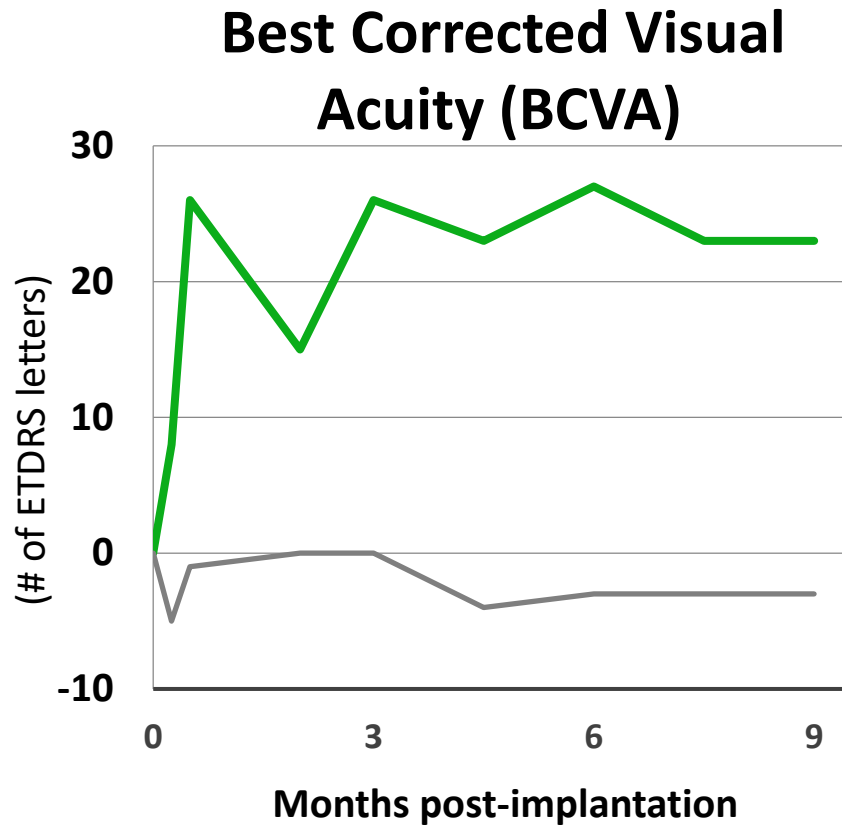
Untreated



Treated



Visual Acuity Case Study (Subject 602)



Phase 1/2a Clinical Trial Highlights

Treatment with OpRegen has been well-tolerated



Structural Improvement

Some patients show signs of structural improvement in the retina and decreases in drusen density

- Photoreceptor layer and ellipsoid zone assumed a more regular structural appearance in areas of the transition zone where cells were administered



Encouraging Data

Recent data from patients with earlier-stage disease and better baseline vision is encouraging

- Evidence of durable transplantation and structural improvement within the retina
- Some improvements in visual acuity noted



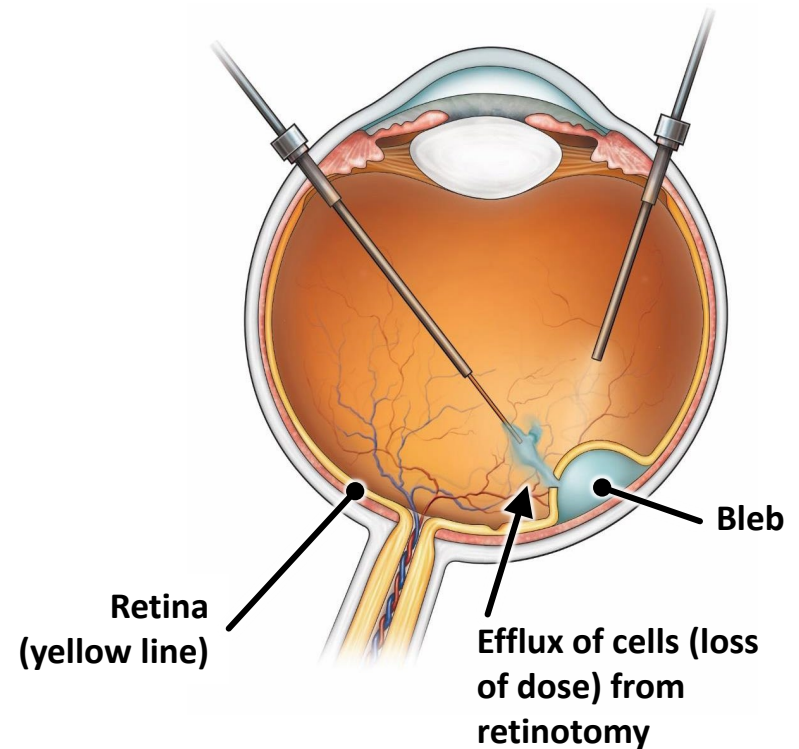
No Unexpected Adverse Events

No unexpected adverse events or treatment-related systemic serious adverse events reported through 16 patients

- Current subjects are being dosed with an improved delivery device (Orbit SDS), eliminating the need for a vitrectomy and retinotomy

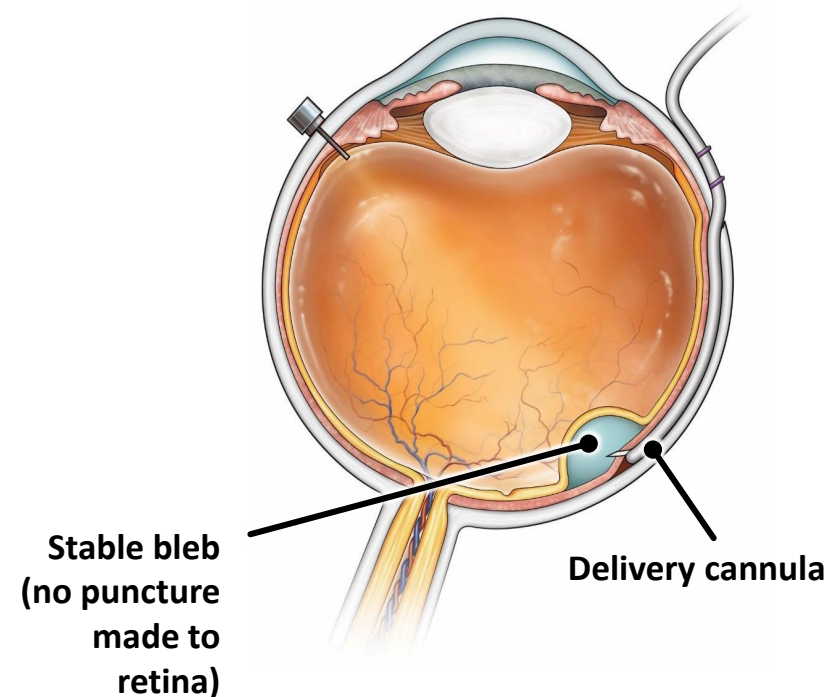
Subretinal Delivery Challenges

- **Current standard (transvitreal) techniques reach the subretinal space by vitreous removal (vitrectomy) and incision of the retina (retinotomy)**
- **Transvitreal delivery complications may include:**
 - Retinal tear or detachment
 - Cataract formation
 - Enlarged retinotomy at bleb area
 - Efflux of delivered cells
 - Dose variability
 - Surgeon procedural variability



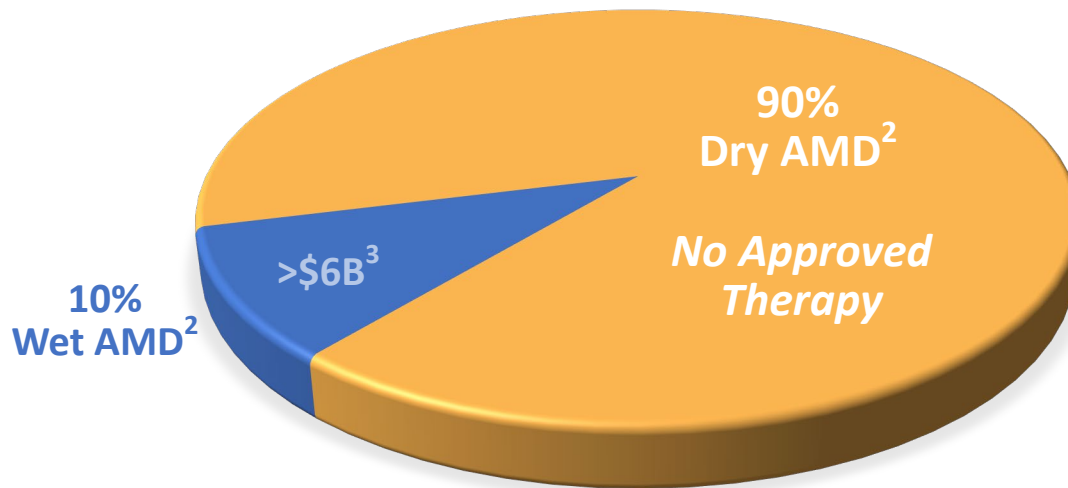
Subretinal Delivery Solution

- **Lineage has begun using a vitrectomy-free subretinal injection device:**
 - “For subretinal delivery of RPE cells for the treatment of all stages of dry AMD including geographic atrophy”
- **Originally developed by Janssen**
- **Device provides access to the subretinal space via a suprachoroidal route**
- **Avoids puncturing the retina and creates a stable bleb of delivered cells**
- **Addresses two major issues; dose control and adverse events due to efflux**



Significant Market Opportunity

- AMD afflicts ~11 million people in the United States
 - 90% of AMD patients have the dry form
 - ~\$6B in sales of approved Wet AMD therapies²: Lucentis[®] and Eylea[®]
 - Currently, there are no approved therapies for Dry AMD





Cell Therapy for Spinal Cord Injury

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Lucas' Story

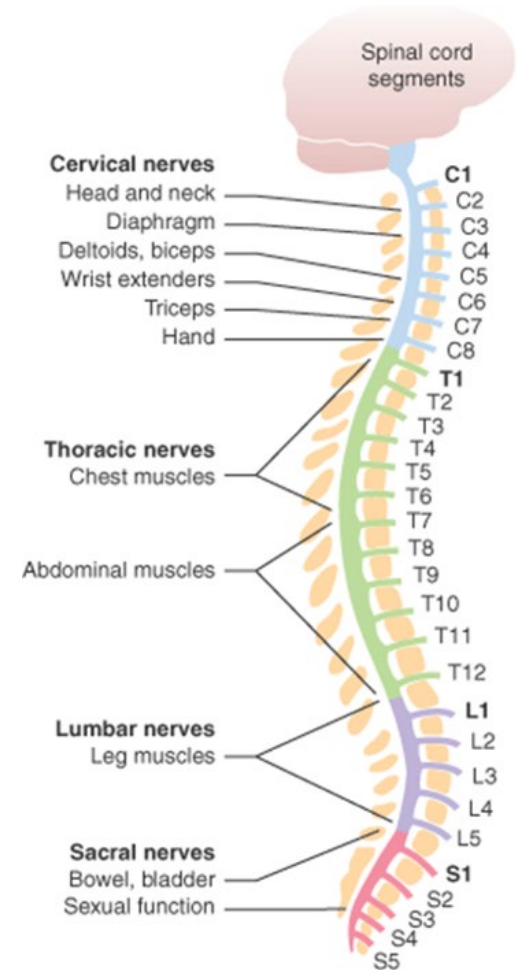


Lucas Linder, an OPC1 clinical trial participant, was paralyzed from the neck down following an accident.

The next year, he threw out the first pitch at a Major League Baseball game.

Spinal Cord Injury (SCI)

- SCI creates a significant burden for patients and caregivers*
 - 67% of patients are unemployed 10 years post-injury
 - Lifetime direct healthcare costs can reach \$5 million for one patient
- Motor level improvements can translate into clinically significant improvements in self-care and reductions in cost of care
- The therapeutic goal is to restore arm, hand, and finger function, increasing independence and quality of life



OPC1 Overview

- **OPC1 is a population of non-patient derived oligodendrocyte progenitor cells (OPCs)**
- **OPCs are precursors to the cells which provide electrical insulation for nerve axons in the form of a myelin sheath**
- **OPC1 has RMAT and Orphan Drug Designations from the FDA**
- **Program has received >\$14M from CIRM**

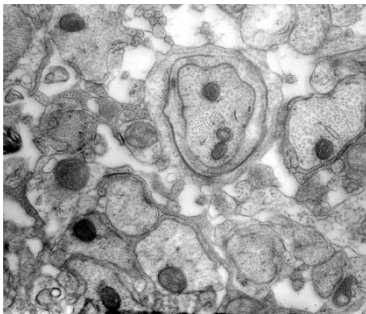


OPC1 Injection Procedure

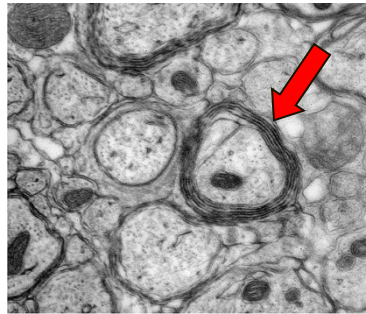
OPC1 Potential Mechanisms of Action

Myelination of axons

shiverer mouse

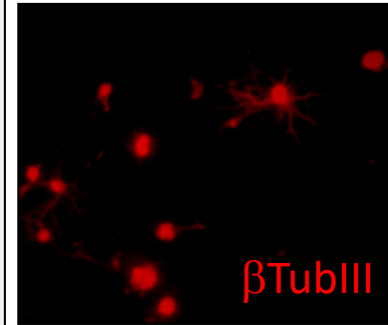


shi mouse + OPC1

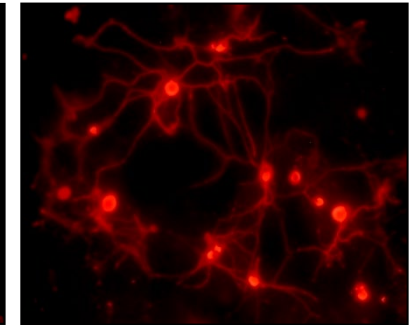


Secretion of neurotrophic factors

Control Media

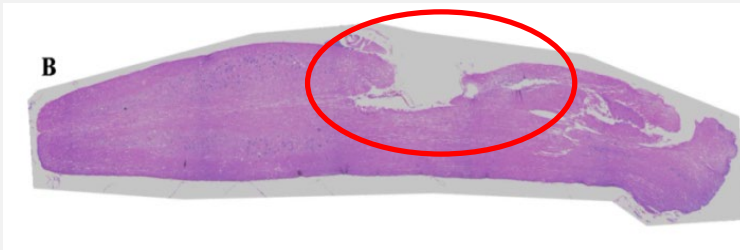


OPC1

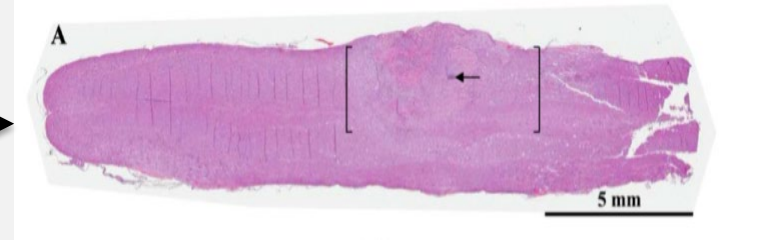


Prevention of Cavitation

Control



OPC1



Completed Studies in Spinal Cord Injury

Pre-Clinical

28 Animal Studies

- Cells survive in the spinal cord
- Improves locomotor activity
- Reduces parenchymal cavitation
- Migrates up to 5cm in spinal cord
- No distribution outside of CNS
- Does not increase mortality
- Does not induce systemic toxicity
- Does not produce teratomas

Clinical (n=30)

Phase 1 Thoracic Study

- Long-term follow up has shown no evidence of adverse changes in any subjects

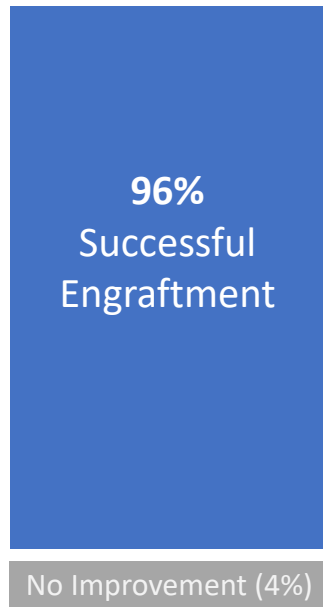
Phase 1/2a Cervical Study

- 25 subjects received up to 20M cells
- Evidence of durable cell engraftment
- Increased motor recovery
- No serious adverse events (SAEs)

Safety and Efficacy from OPC1 Phase 1/2a Study

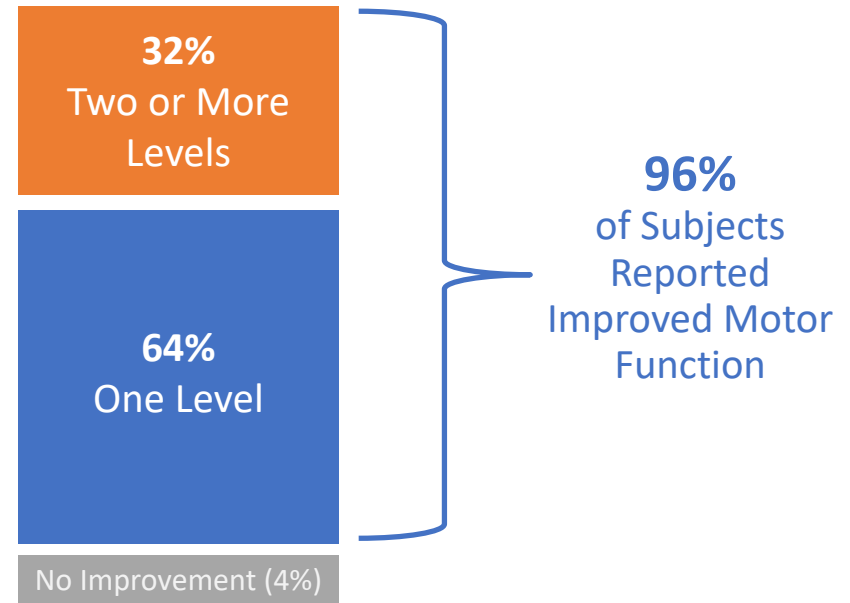
Cell Engraftment

(cohorts 2-5 at 12 months, n=22)



Motor Function Gain

(cohorts 2-5 at 12 months, n=22)



To date, there have been no serious adverse events related to the OPC1 cells



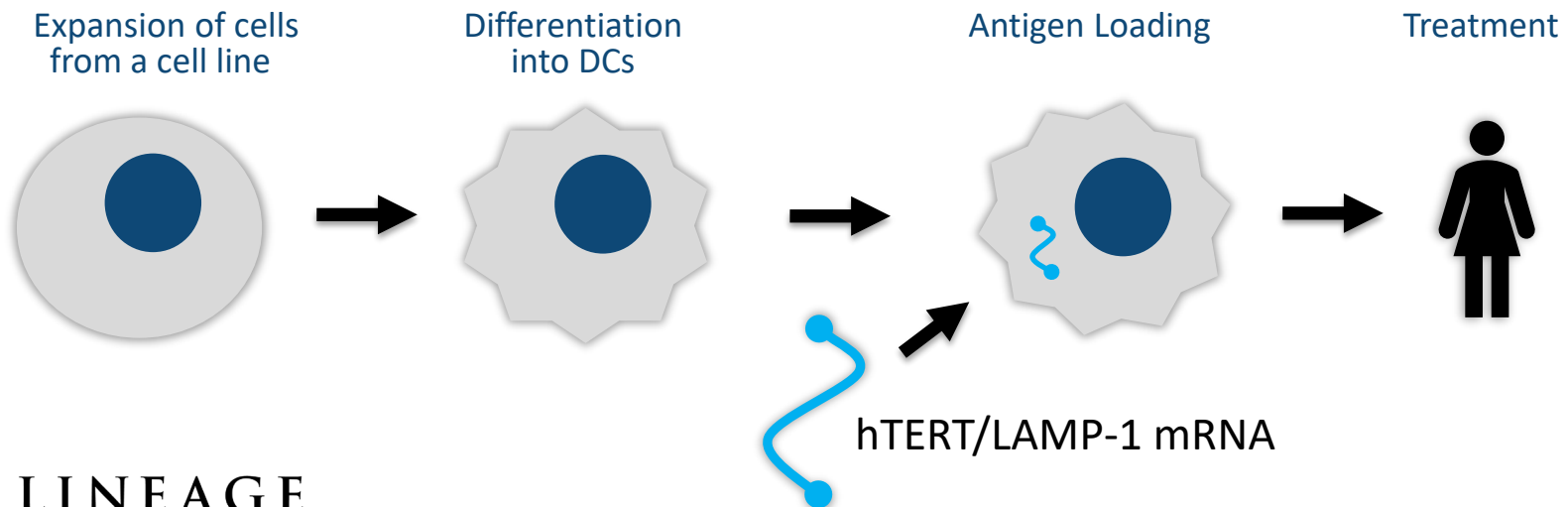
Cell Therapy for Cancer

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VAC Immuno-Oncology (I-O) Program

- VAC platform uses mature dendritic cells (DC) to increase a patient's tumor response
- Treatment is an allogeneic vaccine; cells are manufactured from a pluripotent cell line and not derived from the patient
- Mature dendritic cells are manufactured and loaded with an antigen present in >85% of all cancers and an MHC-presenting sequence, to stimulate CD8+ (cytotoxic) and CD4+ (helper) T cell responses
- Targeted education of T cells increases immune response and tumor cell destruction



VAC2 Clinical Program

- Partnered with Cancer Research UK, which is responsible for the costs and conduct of manufacturing and the clinical trial
- Primary endpoint: safety and tolerability
- Secondary objectives: immunological response and survival
- Enrollment is ongoing



Potential Advantages of the VAC2 Approach

Attribute	VAC2
Single master cell bank for scalability and consistency	✓
Available 'off-the-shelf', on demand	✓
No known significant off-target effects	✓
Low AE-related cost of treatment	✓
Lower anticipated COGS than CAR-T	✓
Use in combination with chemotherapy	✓
Use in combination with immune checkpoint inhibitors	✓

VAC2 was designed to overcome limitations of first-generation I-O combinations and autologous approaches, while providing cost and safety advantages in combination or competition with CAR-T, CTL4, or Immune Checkpoint Inhibitors (ICIs).



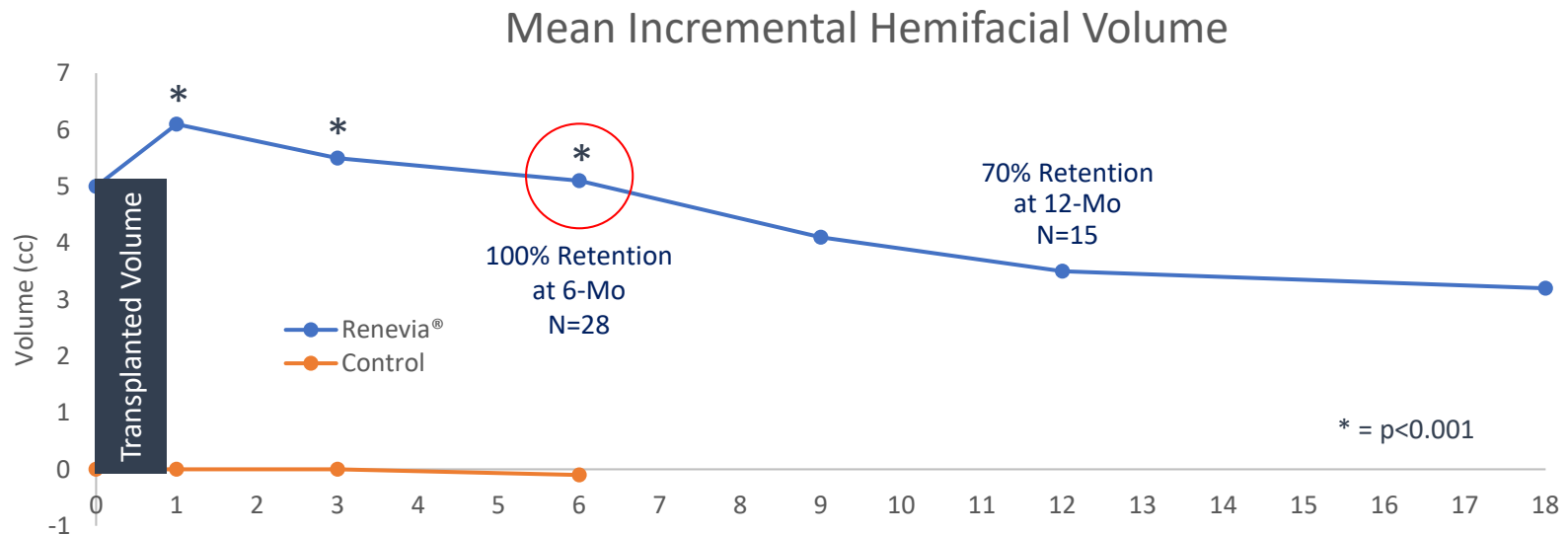
Renevia[®]

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Renevia®

- A proprietary cell transplant matrix tested in combination with autologous fat stromal vascular fraction cells for facial volume augmentation
- 50-patient, HIV-Associated Lipoatrophy Study
 - Increase in hemifacial volume measured by 3D image scan at 6 months
- Submitted for CE mark in Europe; response expected 2H 2019

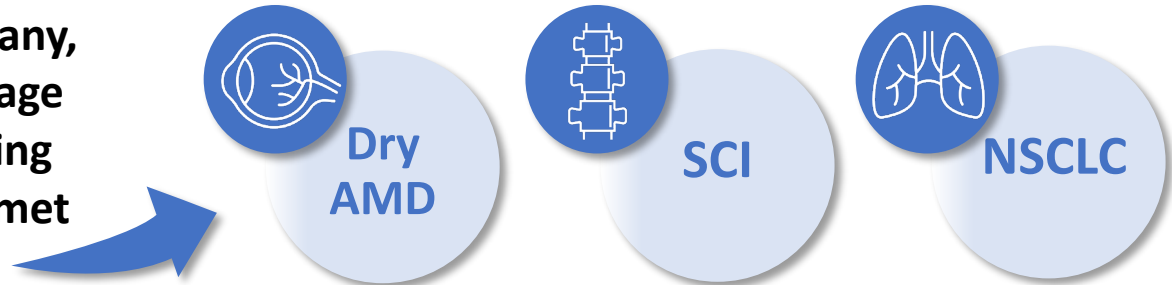


Financial Overview

- **Cash and cash equivalents and marketable securities**
 - **\$16.7 million** (as of 6/30/2019)
- **Value of Equity Holdings in OncoCyte Corporation (OCX)**
 - **\$21.5 million** (based on closing stock price on 9/5/2019)
- **Convertible promissory note due from Juvenescence**
 - **\$22.9 million** (as of 6/30/19, matures Aug 2020)
- **Market Capitalization**
 - **~\$139 million** (as of 9/5/2019)
- **Employees**
 - **75** (as of 9/5/2019)

Lineage Investment Highlights

A leading cell therapy company, developing three clinical-stage programs, each transplanting specialized cells to treat unmet medical needs



Significant Milestones

- ✓ Implemented cost efficient business model focused on clinical development of cell therapy candidates
 - Hired new CEO, CFO, CMO, General Counsel and VP of Business Development
 - Completed corporate rebranding and relocation to lower cost locale (Carlsbad, CA)
- ✓ Strengthened extensive IP portfolio with the issuance of 3 new U.S. patents
 - Method of reducing cavitation in patients with acute SCI
 - System for generating immunogenic dendritic cells
 - Method of generating oligodendrocyte progenitor cells (OPCs) for treatment of SCI
- ✓ Awarded \$2.5M grant from Israel Innovation Authority for OpRegen development and SBIR grant from NIH for Innovative Vision Restoration Program



The future of cell therapy.

www.lineagecell.com

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