LINEAGE
CELL THERAPEUTICS

The future of cell therapy.

H.C. Wainwright Bioconnect Conference

January 10, 2021

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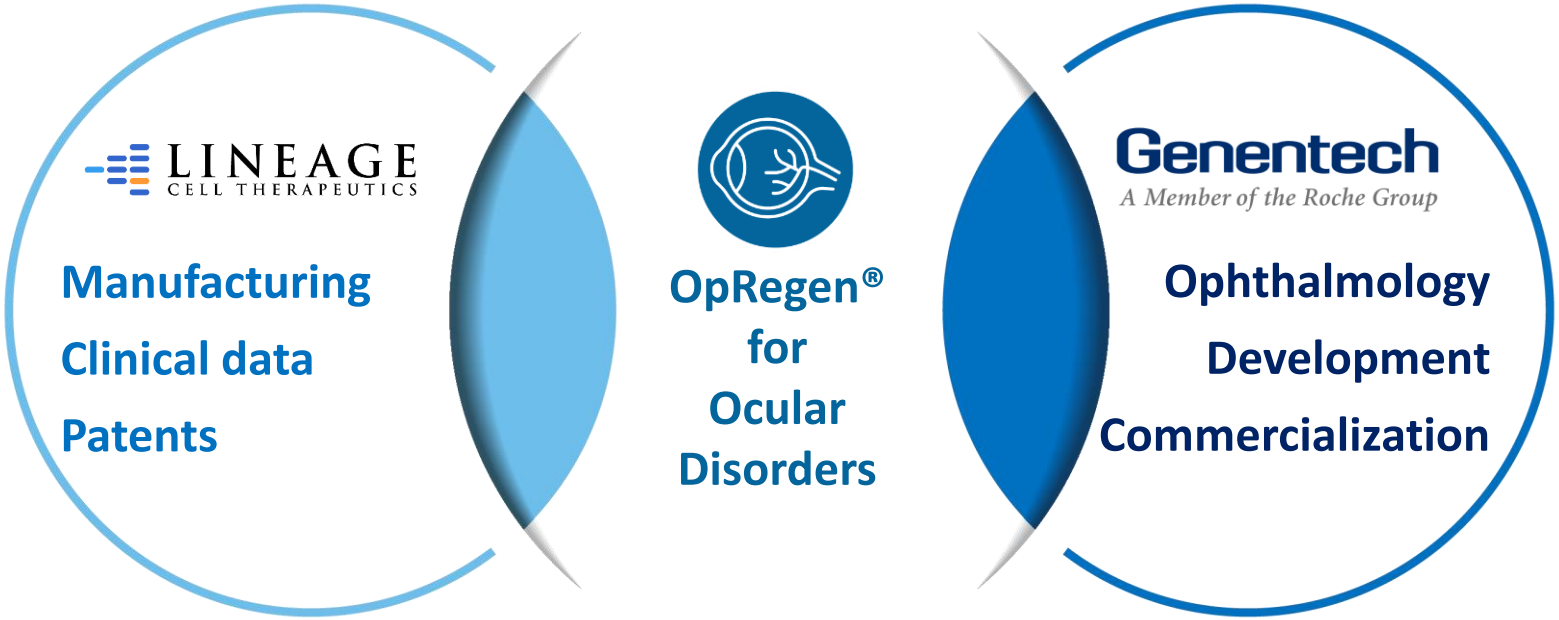
Worldwide Collaboration in Ocular Disorders

Genentech
A Member of the Roche Group

Exclusive collaboration for the development and commercialization of OpRegen for the treatment of ocular disorders

- **$50 million up front; double-digit tiered royalties; $620 million of potential payments**
- **Lineage to complete ongoing study and continue certain manufacturing activities**
- **Genentech responsible for clinical development and commercialization**



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"We aim to pioneer a new branch of medicine, based on transplanting specific cell types into the body"

Business Overview

Company Overview

Innovative Platform	Manufacturing and transplanting *specific cell types* from a single pluripotent cell line; scalable "off the shelf" cell transplants for multiple conditions
Validating Partnerships	Genentech – A Member of the Roche Group; CIRM – California Stem Cell Agency; Cancer Research UK
Three Clinical Programs	**OpRegen:** Dry Age-Related Macular Degeneration (dry AMD) **OPC1:** Spinal Cord Injury **VAC2:** Oncology (NSCLC)
Differentiated Data	Four cases of *retinal tissue restoration* in dry AMD patients One-third of spinal injury patients *gained at least 2 levels* of motor function *Potent* induction of immune responses observed in advanced cancer patients
Market Opportunity	Billion-dollar commercial opportunities with no or few treatment options
Financial Position	~$65.1 million in cash and marketable securities as of Sep 30, 2021*
Market Capitalization	~$347 million°

Does not include Genentech $50M upfront payment

°*Based on common shares outstanding as of 11/5/2021*

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Novel Clinical Cell Therapy Pipeline

LINEAGE	PROGRAM	PHASE 1	PHASE 2	PHASE 3	PARTNERS
Ophthalmology	**OpRegen®** Dry AMD with Geographic Atrophy (GA)	24 patients treated			Genentech A Member of the Roche Group
Demyelination	**OPC1** Spinal Cord Injury (SCI)	30 patients treated			CIRM CALIFORNIA'S STEM CELL AGENCY
Immuno-oncology	**VAC2** Non-Small Cell Lung Cancer (NSCLC)	7 patients treated			CANCER RESEARCH UK

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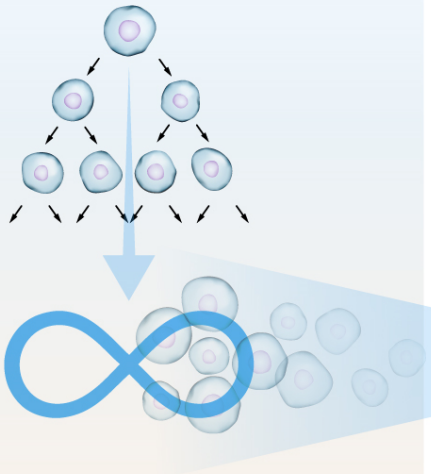
Lineage Technology Platform – Allogeneic Cell Transplants

Expansion

- Product development starts from a frozen vial of self-renewing stem cells
- These pluripotent cells can become any cell type in the body when provided with the correct instructions



Differentiation

- Lineage's proprietary process, honed from decades of institutional experience, creates only the cell type which is desired
- No alterations are made to the cell's DNA
- In-house cGMP manufacturing allows for commercial-scale production from a single vial of stem cells

Development

- Value is created by developing and implementing clinically and commercially-viable product attributes
- Pipeline expands by broadening indications or adding additional cell types

Retinal Cells → **OpRegen**

Spinal Cord Cells → **OPC1**

Immune Cells → **VAC2**

Other Pipeline Programs

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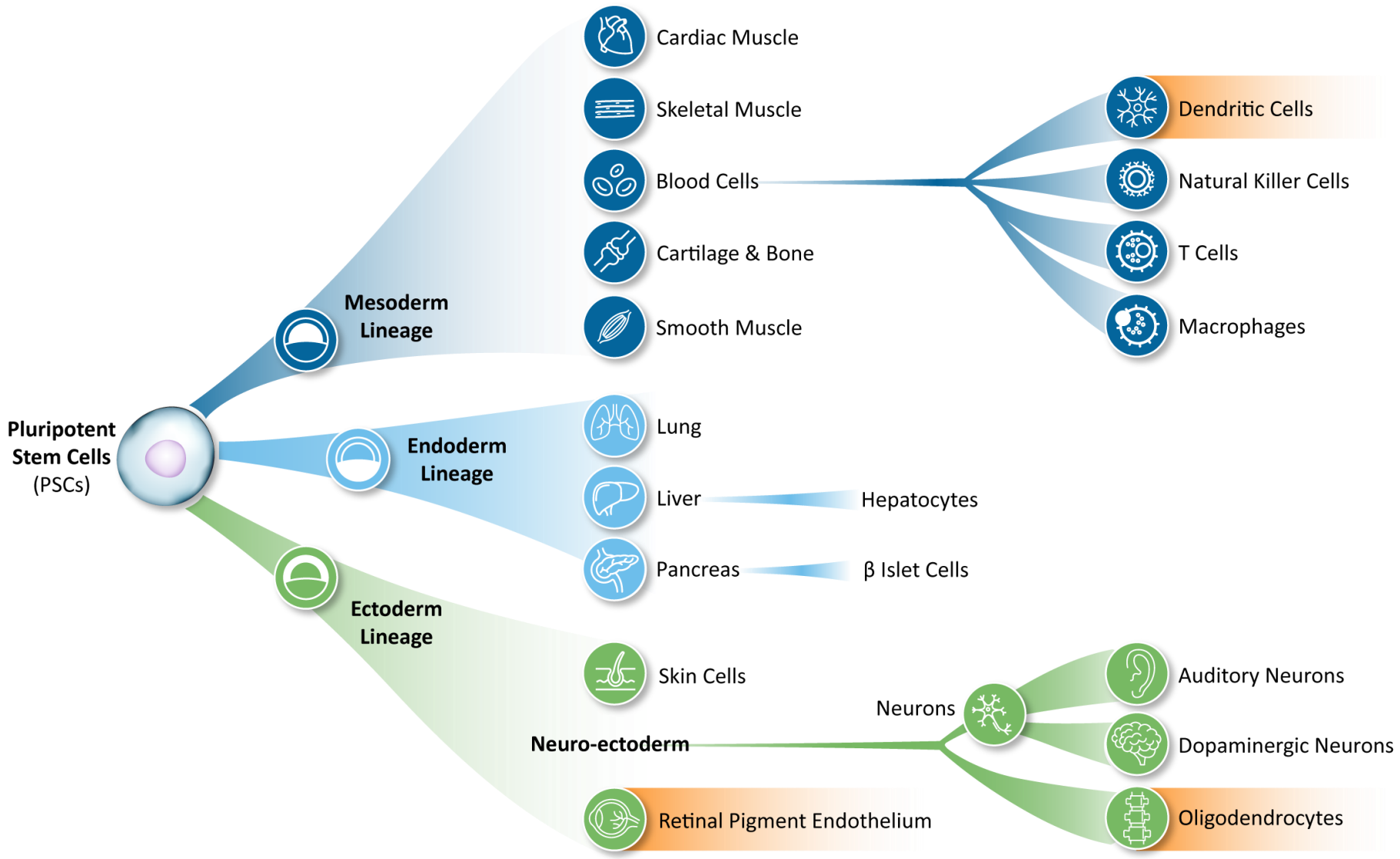
Future Product Candidate Opportunities



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AMD is the leading cause of irreversible vision loss in the US

Source: aao.org

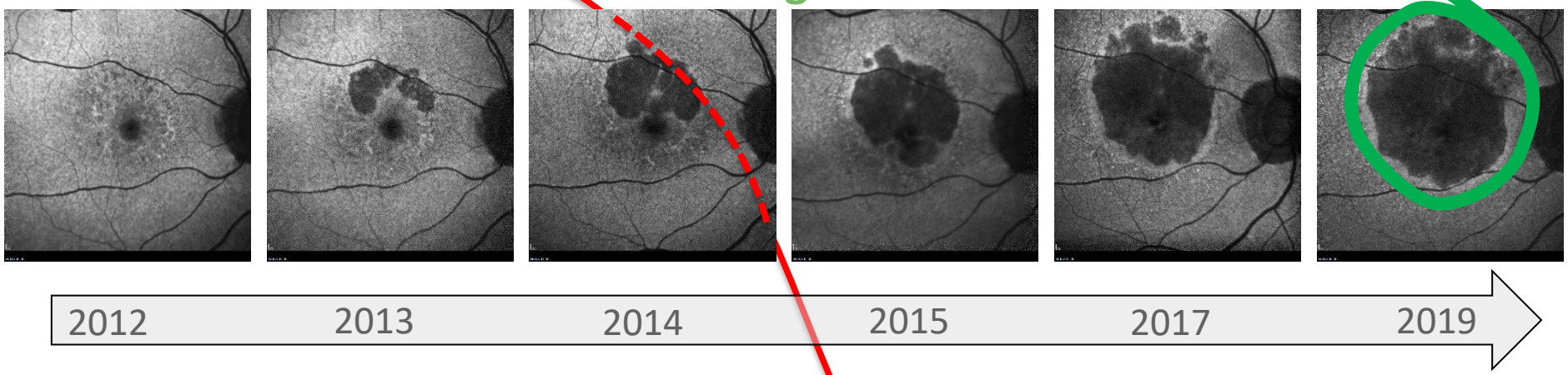
OpRegen®: RPE Cell Transplants to Treat Dry AMD

Dry AMD Can Lead Rapidly to Blindness

Visual acuity over time…

20/20 (normal)

The area of geographic atrophy or "GA" grows larger as retinal cells die



20/200 (legally blind in 3 years)

20/640

Dry AMD involves the progressive loss of retina cells, which can lead rapidly to blindness

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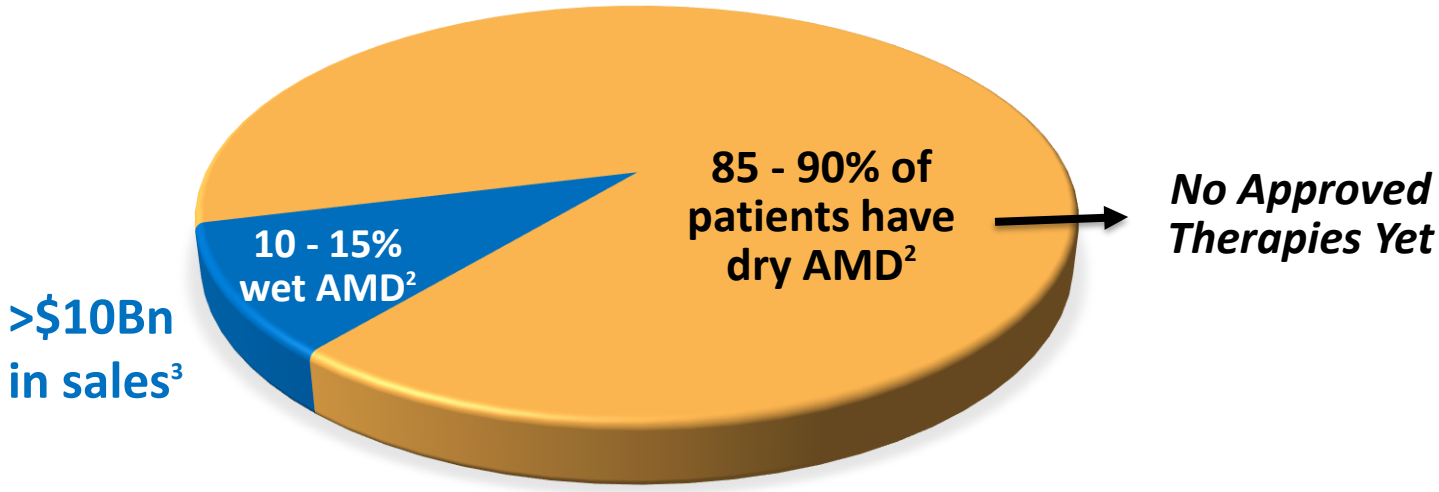
Image courtesy of Jordi Monés, MD, PhD

Multi-Billion Dollar Market Opportunity in the U.S.

Age-related Macular Degeneration (AMD) in all forms afflicts ~11 million people in the United States

Type of AMD	% of AMD Cases	FDA Approved Therapies
Wet AMD	10 – 15%	Lucentis & Eylea ($10 Billion in annual sales)
Dry AMD	**85 – 90%**	**None**



Sources: (1) Bright Focus Foundation. Macular Degeneration Facts & Statistics: Bright Focus Foundation. http://www.brightfocus.org/macular/about/understanding/facts.html; (2) JM Seddon, Epidemiology of age-related macular degeneration. (AP Schachat, S Ryan eds.) Retina, 3rd ed. St. Louis, MO: Mosby; 2001;1039-50; (3) 2018 product sales summary based on publicly reported revenue figures for Lucentis and Eylea.

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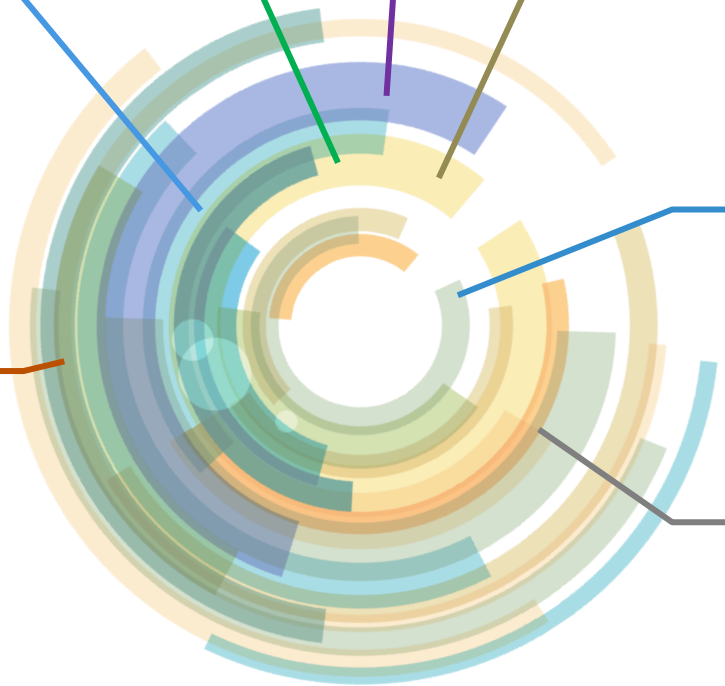
Dry AMD Competitive Landscape

Cell Therapy
OpRegen (Ph1/2)
CPCB-RPE1 (Ph1/2, Regenerative Patch Tech.)
ASP7317 (Ph1, Astellas) (Enrollment Paused)
jCell (Preclinical, jCyte)

Visual cycle modulation
ALK-001 (Ph. 3, Alkeus)
FAILED
fenretinide (Sytera)
emixustat (Acucela)
OT-551 (Othera)

Anti-inflammatory
Complement inhibition location and molecule:
ANX007 (Ph2, Annexon)
APL-2 (Ph3, Apellis)
CB2782 (Preclinical, Catalyst)
Zimura (Ph3, Iveric bio)
ALXN1720 (Ph1, Alexion)
HMR59 (Ph2, Hemera)
danicopan (Ph1, AstraZeneca RD)
Ionis-FB-LRX (Ph2, Ionis)
NGM621 (Ph2, NGM Bio)
FAILED
eculizumab (Alexion)
tesidolumab (Novartis)
lampalizumab (Genentech/Roche)
CLG561 (Novartis)

Toxic by-product reduction
Prevent Amyloid Aβ oligomer assembly:
GAL-101 (Ph1, Galimedix)
ALZ-801 (Preclinical, Alzheon)
Reduce DHA peroxidation:
RT011 (Preclinical, Retrotope)
FAILED
Glatiramer acetate (Teva)
RN6G (Pfizer)
GSK933776 (GSK)



Gene Therapy
Gyroscope (Ph1/2)
Hemera/Janssen (Ph1)
Novartis (Preclinical)

Neuroprotection
Repair mitochondrial dysfunction/oxidative stress:
elamipretide (Ph2, Stealth)
risuteganib (Ph2, Allegro)
photobiomodulation (Ph N/A, LumiThera)
brimonidine tartrate (Ph2, Allergan)
FAILED
NT-501 (Neurotech)
tandospirone (Alcon)
OT-551 (Othera)

Other approaches
Inflammasome Inhibition:
kamuvudine (Ph1, Inflammasome Therapeutics)
Xiflam (Preclinical, OcuNexus)
Matrix Modulation:
doxycycline (Ph2/3, Oracea)
HtrA1 inhibitor:
FHTR2163 (Ph2, Genentech/Roche)

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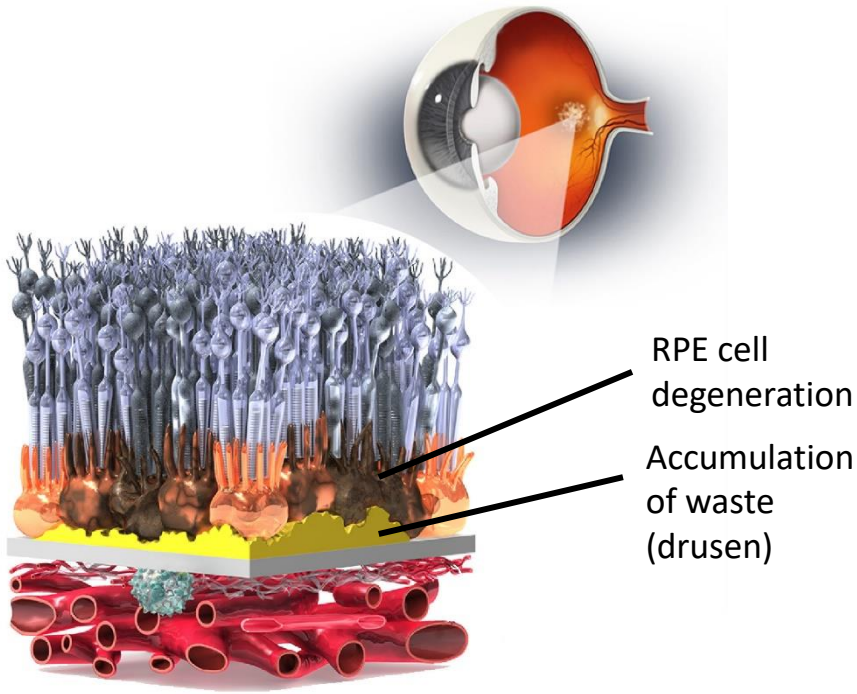
Adapted from https://retinatoday.com/resource/therapeutic-pipeline-for-amd (Accessed August 12, 2021)

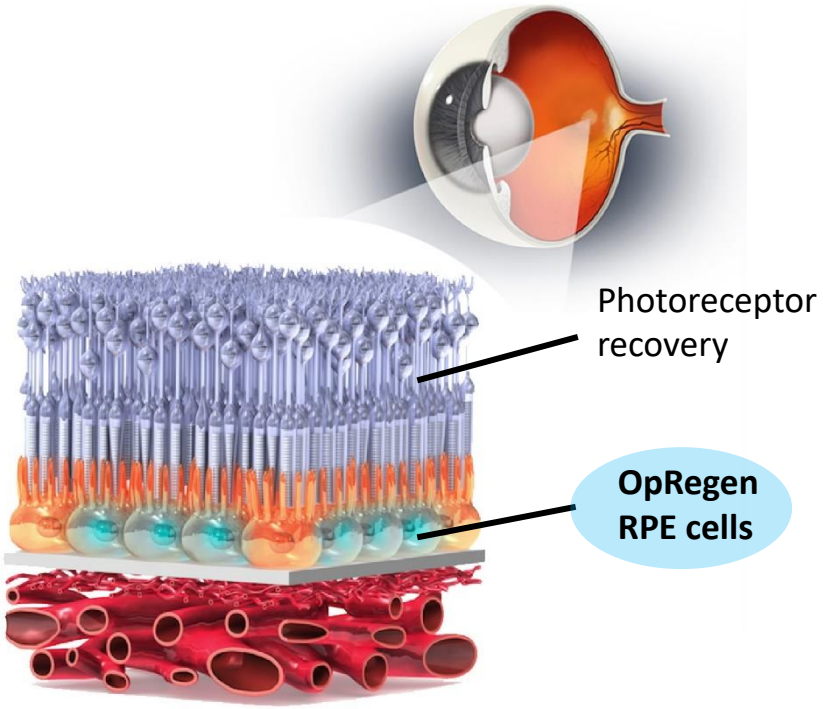
Lineage Approach – OpRegen, an RPE Cell Transplant

Pre-Transplant



Dry (atrophic) AMD involves the loss of retina cells, creating an area of geographic atrophy (GA), which causes impaired vision and blindness

Post-Transplant



OpRegen is an injection of RPE cells beneath the retina to replace lost retinal cells and preserve or improve vision

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Image adapted from scienceofamd.org

Commercially-Suitable Manufacturing Process

- **OpRegen consists of >99% pure RPE cells**
  - Starts from a single, NIH-registered cell line established >20 years ago
  - No genetic modifications are made to the cell's DNA
  - No residual pluripotent ("stem") cells are detectable in clinical material

- **Clinic-ready, immediate-use "thaw and inject" formulation**
  - No dose preparation required
  - From frozen cells to delivery device in 5 minutes

- **Current production scale is 5 billion RPE cells per 3-liter bioreactor**
  - Equal to 2,500 clinical doses/batch
  - Further scale-up can be performed in larger or parallel reactors

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Phase 1/2a Clinical Trial - Promising Interim Results (N=24)

STRUCTURE:

- **4 patients have shown evidence of <u>retinal tissue restoration</u>**
  - All four patients had improved BCVA at 12 months

FUNCTION:

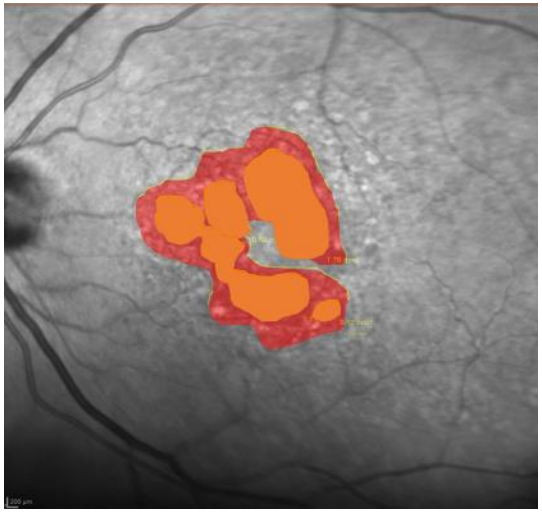
- **Majority of all Cohort 4 patients' treated eyes were at or above baseline visual acuity at 15M, or at last time point available, up to >3y post-treatment**
  - Visual acuity continued to decline in the majority (67%) of untreated eyes

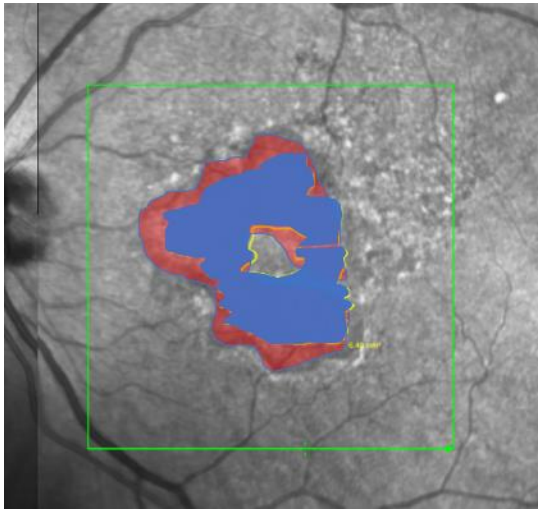
SAFETY, TOLERABILITY, and DURABILITY:

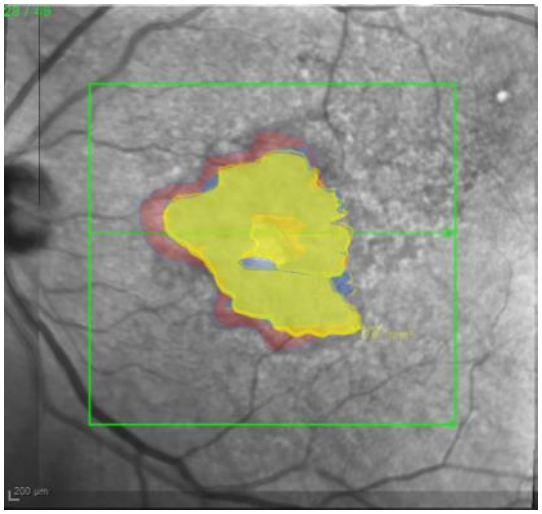
- **OpRegen transplants have been well tolerated with no unexpected AEs or SAEs**
- **Earliest grafts have persisted for more than 5 years**
- **Immunosuppression is removed at ~90 days**
- **Zero cases of rejection (N=24)**

Retinal Restoration – *Smaller* Area of GA, Maintained for Years

Date	Time in Study	Colored area on Figure below	Area mm^2 (SQRT)	Changes in rate of progression from previous	Changes in rate of progression from baseline
May 2017	Minus 1 year	Orange	4.21 mm^2 (2.05)	N/A	N/A
July 2018	Baseline	Red	7.90 mm^2 (2.8)	+ 0.64 mm sqrt/yr	N/A
April 2019	Month +9	Blue	5.74 mm^2 (2.39)	- 0.61 mm sqrt/yr	- 0.61 mm sqrt/yr
October 2019	Month +15	Green	6.48 mm^2 (2.54)	+ 0.30 mm sqrt/yr	- 0.20 mm sqrt/yr
June 2020	Month +23	Yellow	6.52 mm^2 (2.55)	+ 0.015 mm sqrt/yr	- 0.13 mm sqrt/yr







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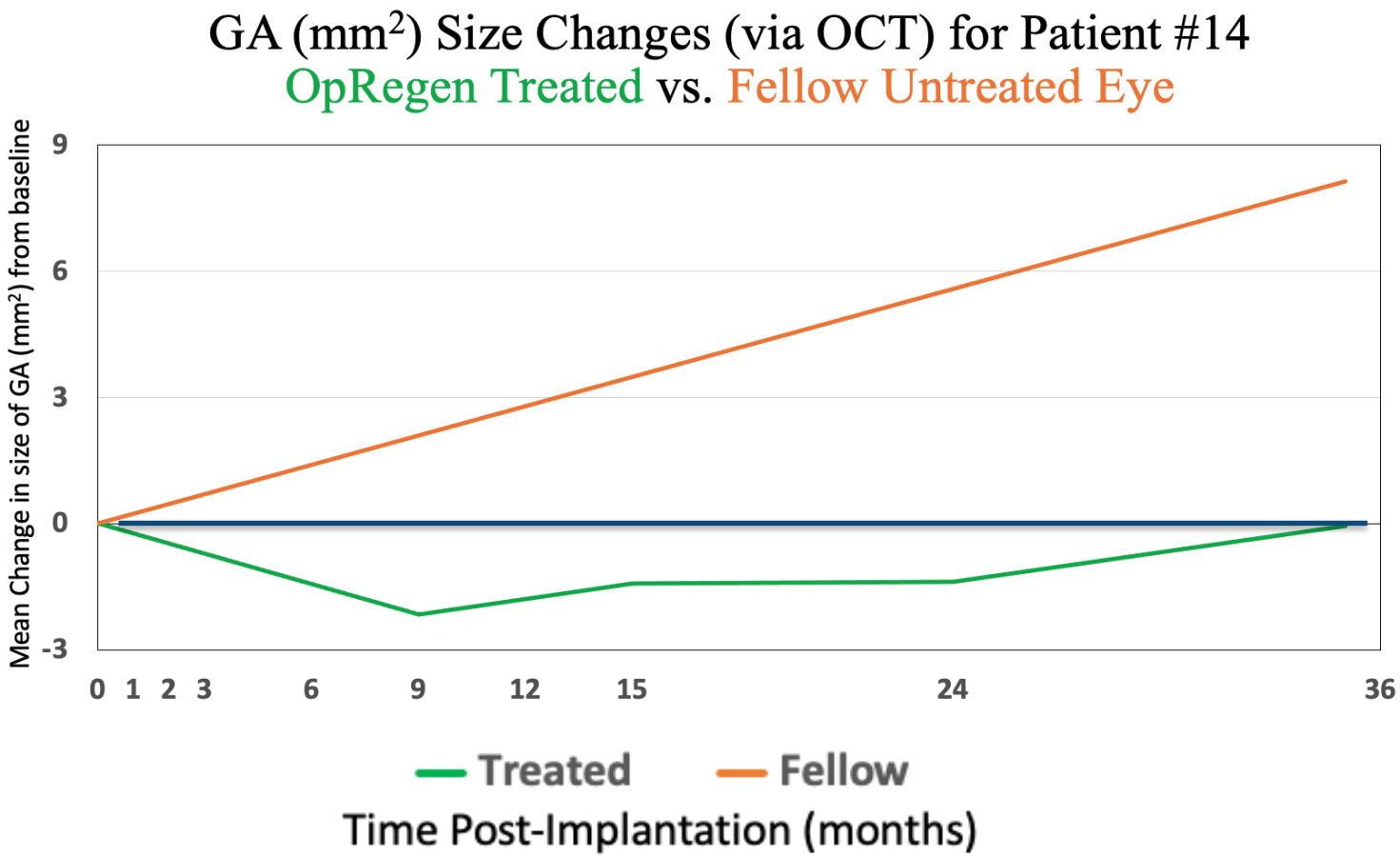
Data presented at 2020 AAO Virtual Meeting

First Reported Case of Retinal Restoration – GA Measurements



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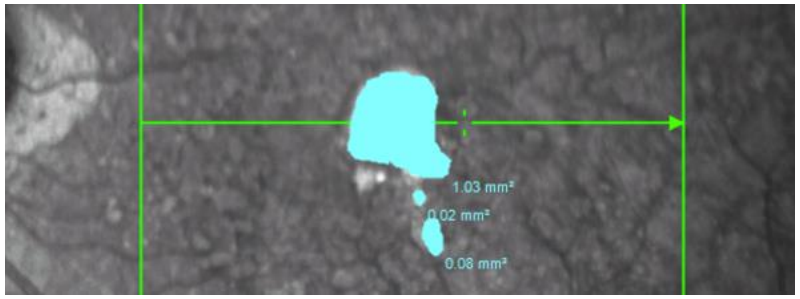
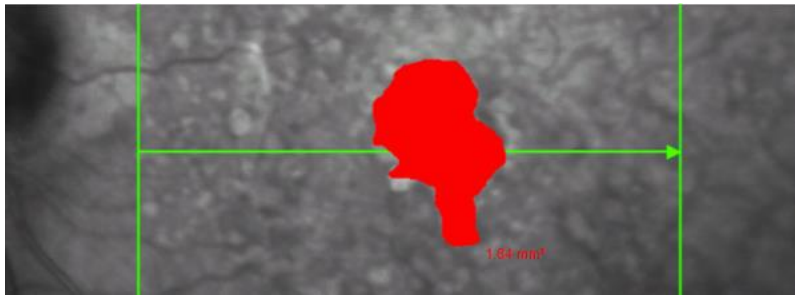
Fourth Case of Retinal Restoration – No GA progression after >1 year



1.06 mm SQRT (1.13 mm^2)

Historic Image

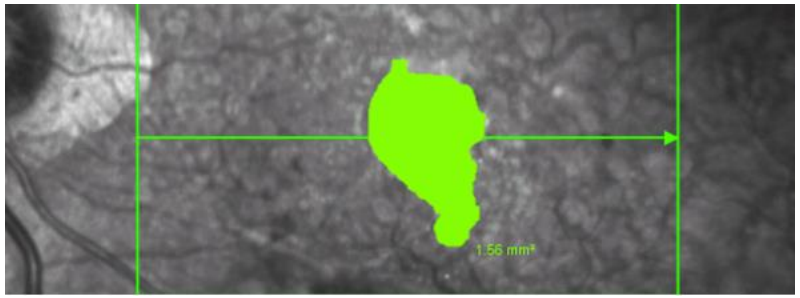
Obtained 16 Months before Baseline Visit



1.28 mm SQRT (1.64 mm^2)

Baseline Image

Rate of Growth from -16 months = +0.165 mm/yr



1.25 mm SQRT (1.56 mm^2)

13.5 Months post-treatment

Rate of Growth from Baseline = - 0.026 mm/yr

The area of atrophy remained smaller than baseline 13.5 months post-OpRegen

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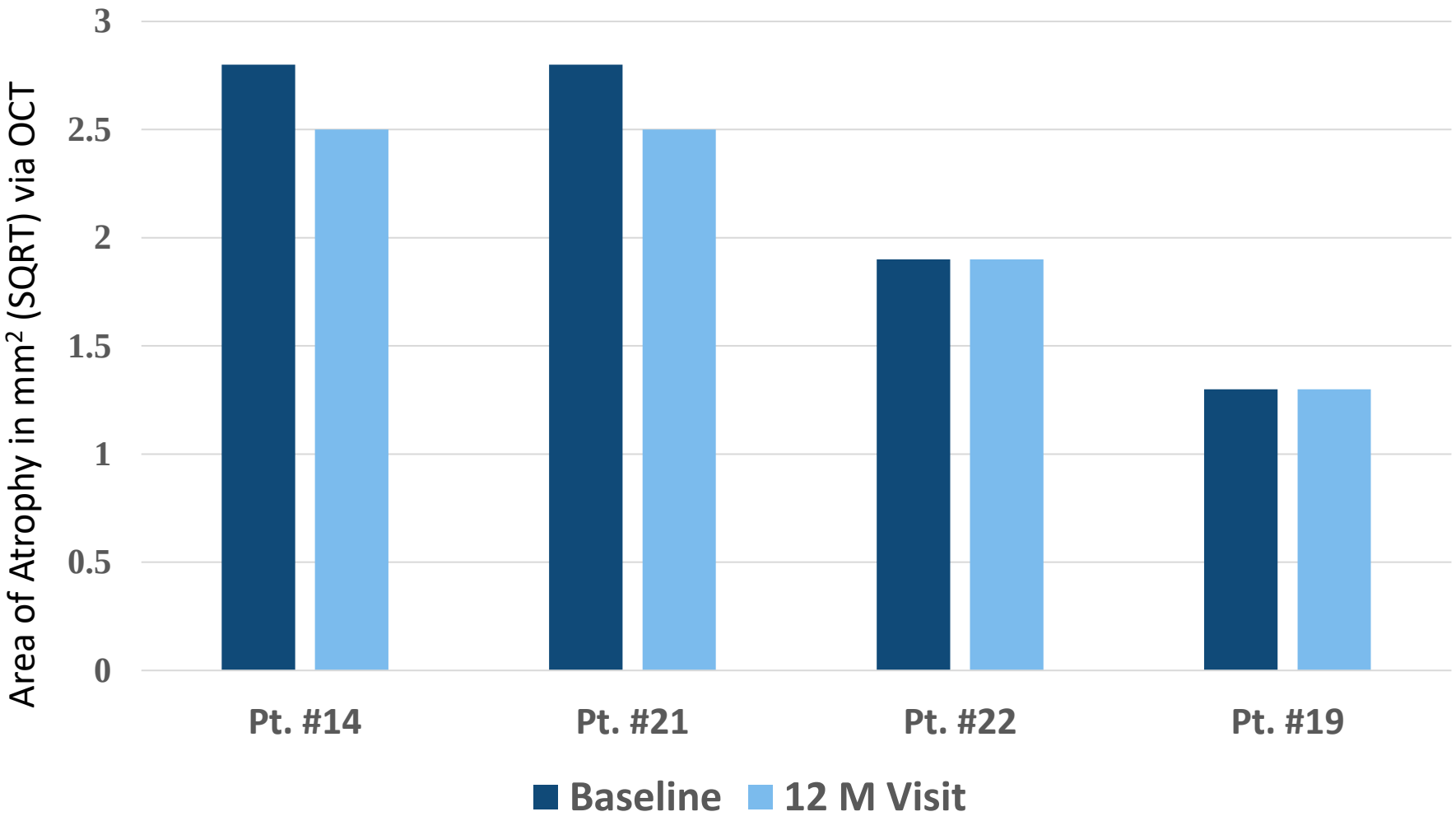
Four Cases of Retinal Restoration – No GA progression after 1 year



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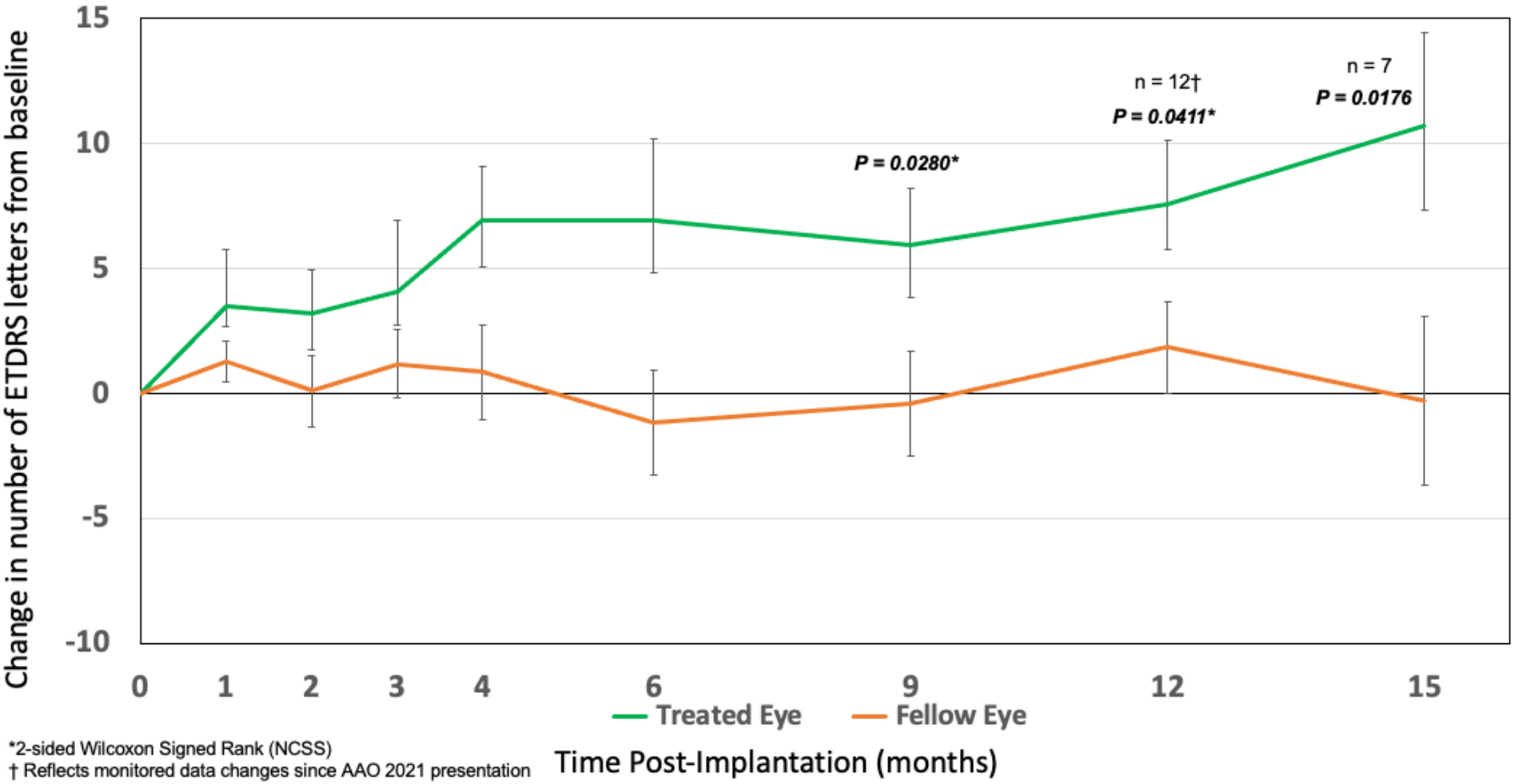
Mean Change (SEM) in Cohort 4 BCVA – Treated and Fellow Eye



*2-sided Wilcoxon Signed Rank (NCSS)
† Reflects monitored data changes since AAO 2021 presentation

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A Multi Billion-Dollar Commercial Opportunity

- **Four cases of retinal restoration reported (only known clinical cases)**
- **Market opportunity is not limited by monogenic deficiencies (e.g. gene therapy)**
- **Treatment has been well-tolerated; meaningful improvements in clinically-relevant metrics such as visual acuity, GA growth, and reading speed**
- **Potential application in other retinal diseases (example: Stargardt's Disease)**
- **Issued patents cover aspects of production, characterization, and formulation**
- **Fast Track designation from FDA**
- **Validating development partnership with global ophthalmology leader, Genentech**

<u>Key Takeaway for the Lineage Approach</u>:

- **Transplanting RPE cells may provide transformational benefits beyond the reach of traditional approaches**

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Lifetime care for an SCI patient can cost nearly $5 million

Source: christopherreeve.org

OPC1: Cell Therapy for Spinal Cord Injuries

Why Spinal Cord Injury (SCI) Matters

Lucas Linder, an OPC1 clinical trial participant, was paralyzed from the neck down. The next year, he threw out the first pitch at a Major League Baseball game.

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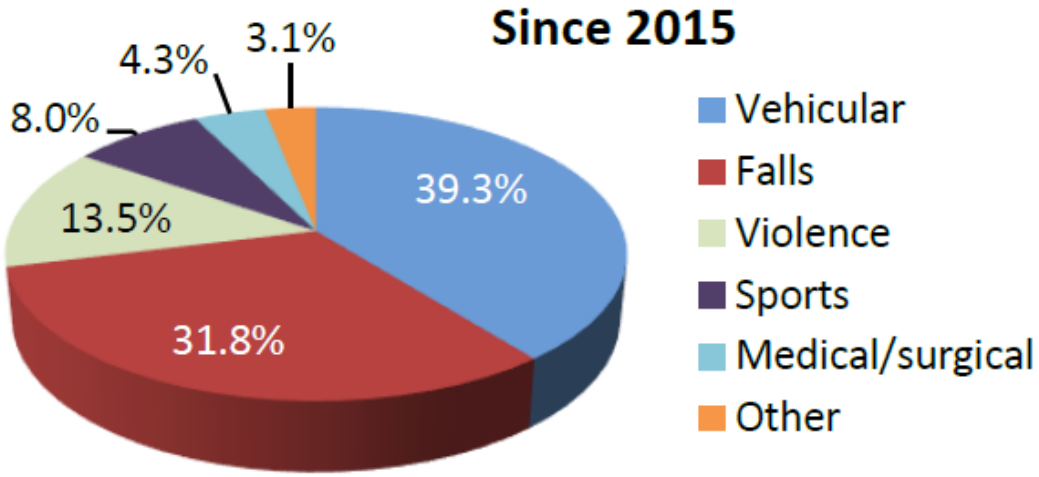
Spinal Cord Injury (SCI) Overview

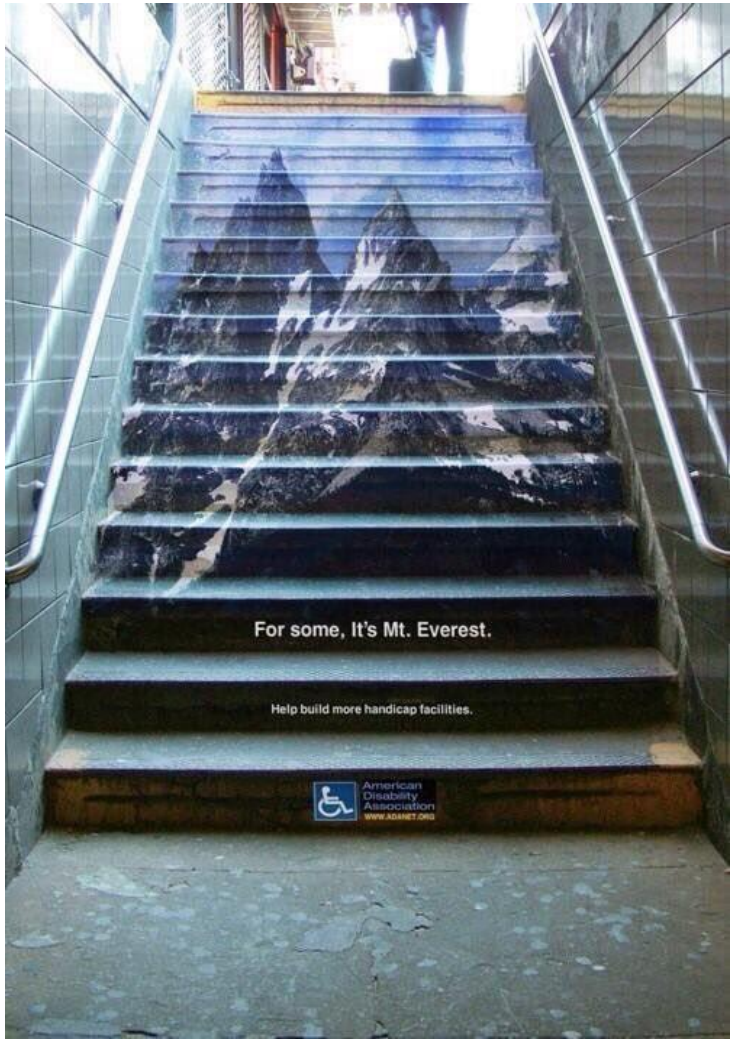
- **Incidence**
  - Approximately 18,000 new cases in the U.S. each year
- **Prevalence**
  - Between 249,000 and 363,000 people in the US
- **Causes**



Source: National Spinal Cord Injury Statistical Center

SCI Burden and Unmet Needs

- **A significant burden for patients and caregivers**
  - 67% of patients are unemployed 10 years post-injury
  - Lifetime healthcare costs can reach $5M for one patient
- **Potential lifelong impairments**
  - Mobility (wheelchair)
  - Pain
  - Re-hospitalizations
  - Infections
  - Ventilator dependency
  - Depression
  - Shortened life expectancy

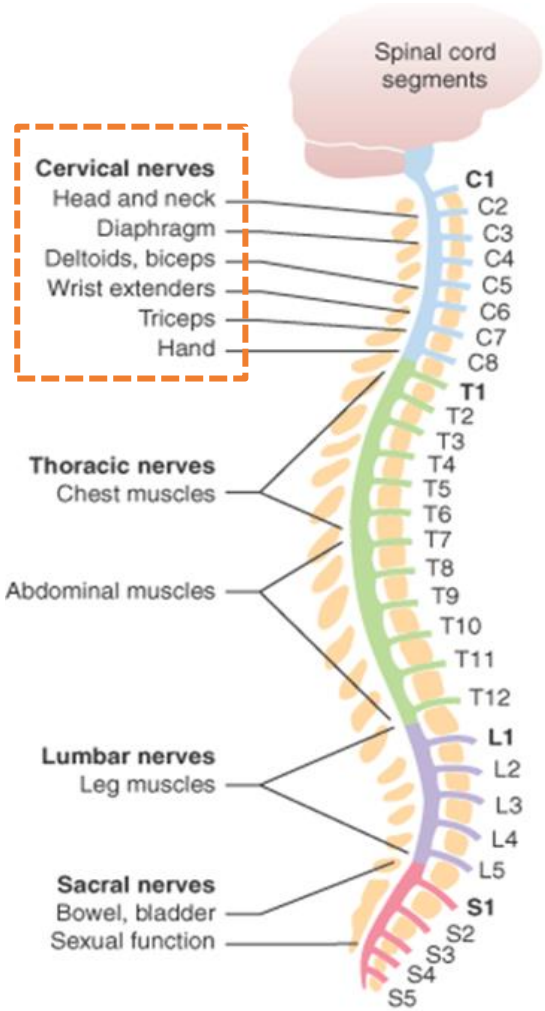


(*) National SCI Statistical Center, 2019 SCI Data Sheet.

SCI Treatment Objectives

Loss of movement is the primary feature of a spinal cord injury

- **Higher-level injuries result in more extensive impairments**
- **Gains in motor function, particularly to the upper extremities, can provide significant benefits in self-care and lower costs of care**
- **The goal of Lineage's cell therapy is to provide additional arm, hand, and finger function, increasing independence and quality of life**

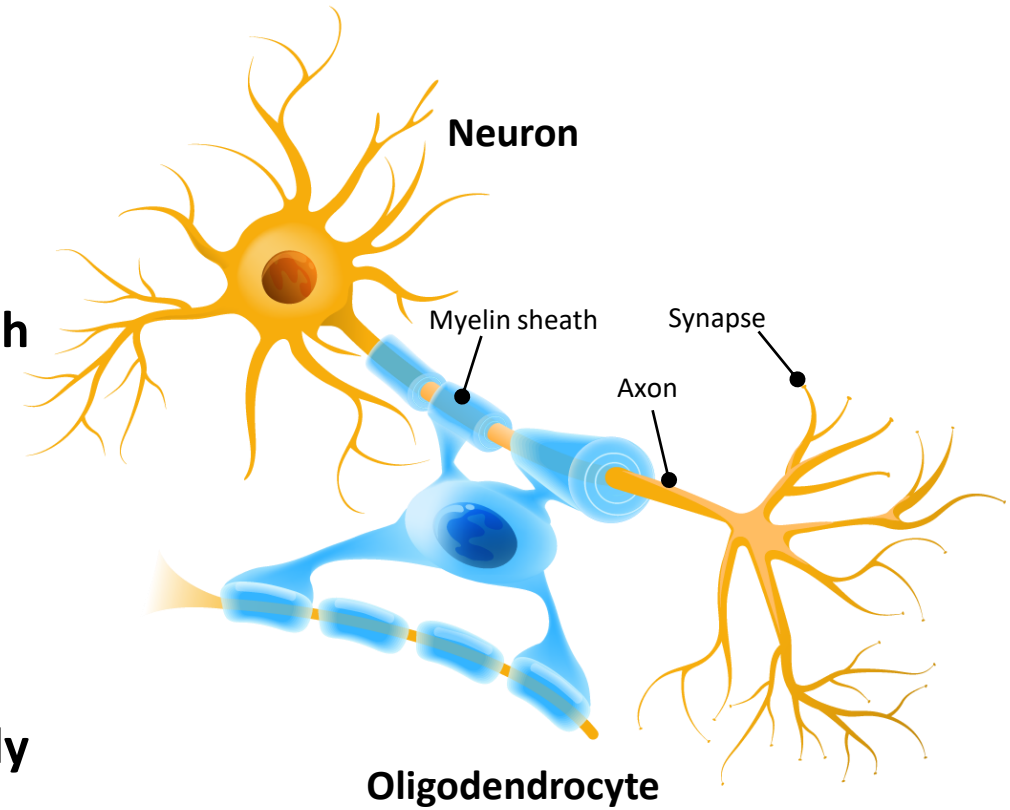


(*) National SCI Statistical Center, 2019 SCI Data Sheet.

OPC1 cells for Spinal Cord Injury

Transplanting oligodendrocytes may provide additional upper extremities function (arms and fingers) and improve quality of life

- **OPC1 is comprised of OPCs (oligodendrocyte progenitor cells)**
- **OPCs are precursors to oligodendrocytes, myelinating cells of the central nervous system, which provide insulation to nerve axons**
- **Myelin is essential for proper function of neurons**
- **OPC1 cells are delivered to the spinal cord, not injected systemically**



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(*) National SCI Statistical Center, 2019 SCI Data Sheet.

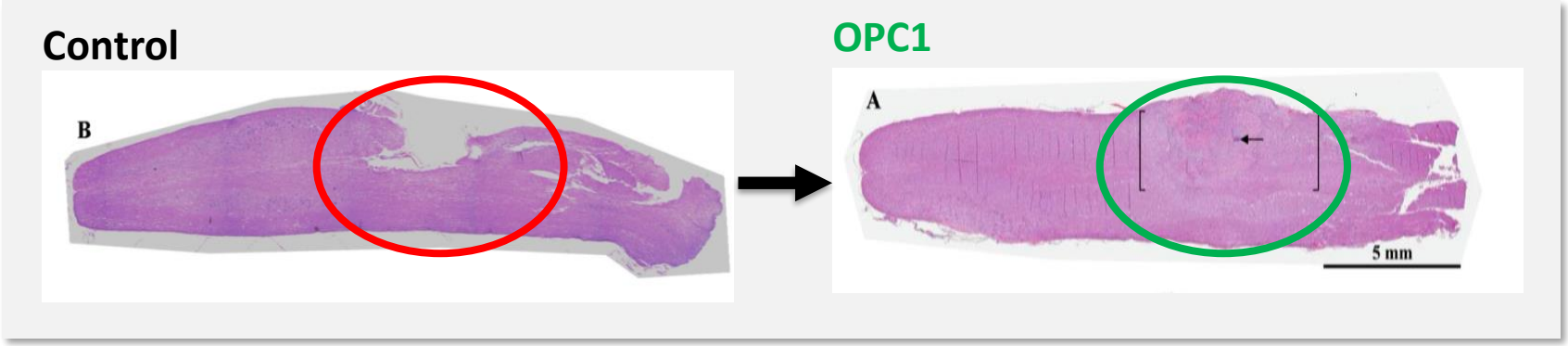
OPC1 Asset Overview

- **OPC1 utilizes targeted cell replacement (similar approach as OpRegen)**
- **Covered by multiple issued patents**
- **RMAT Designation**
- **Orphan Drug Designation**
- **>$14M in support from CIRM (California Institute for Regenerative Medicine)**
- **Potential application to other demyelinating conditions**

OPC1 Transplant Procedure

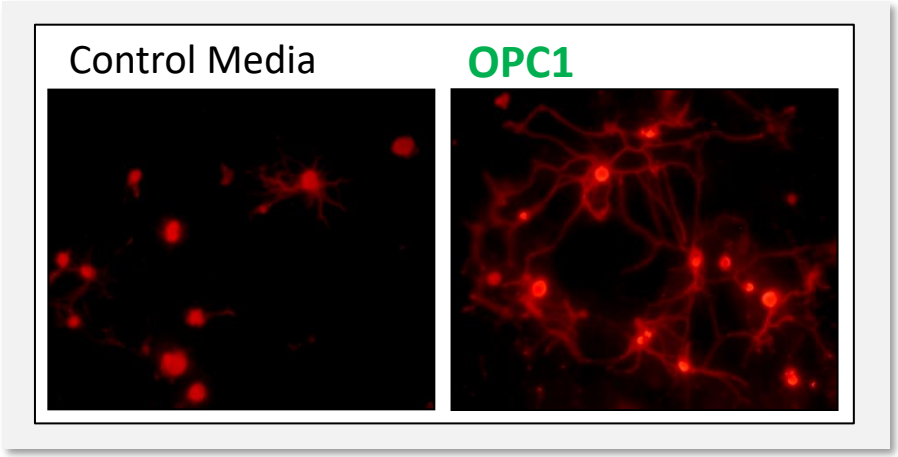
OPC1 Mechanisms of Action

Suppression of Cavitation



Myelination of axons

Secretion of neurotrophic factors



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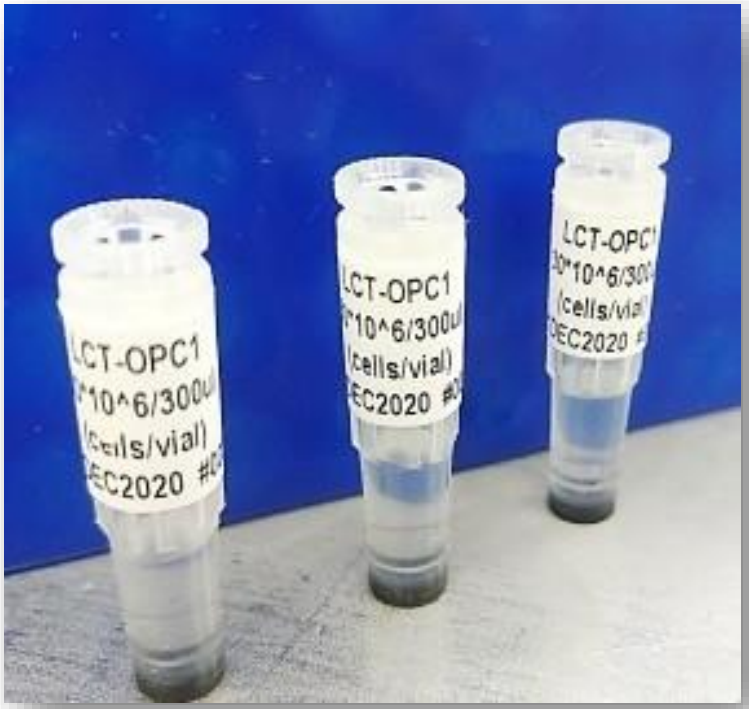
OPC1 for Spinal Cord Injury

- **Lineage's OPCs are derived from a single, NIH-registered cell line**
- **OPC1 cells are "off the shelf" (allogeneic), and not derived from the patient**
  - Patient-derived approaches (iPSC) cannot be generated in time to meet the acute treatment window
- **Treatment occurs <u>3-6 weeks</u> post-injury and includes short-course (60-day) immunosuppression**
- **The OPCs are "ready to use" in a thaw-and-inject formulation, avoiding dose preparation and handling issues**



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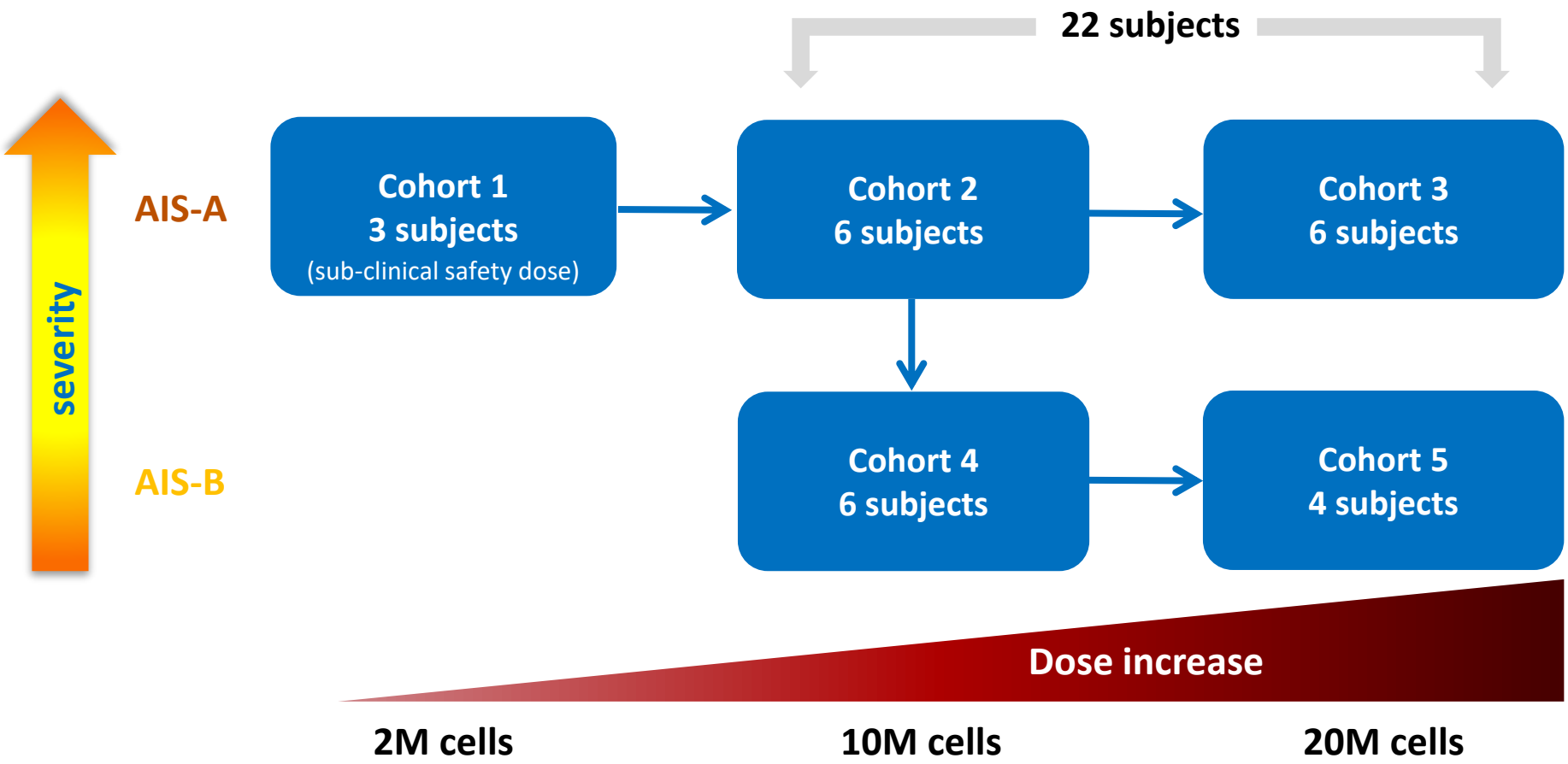
Clinical Trials

- 5 patients treated with thoracic injury (published 2021)
- 25 patients treated with cervical injury (publication expected 2022)



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OPC1 Summary of Adverse Events

Only one AE was deemed possibly related to OPC1*

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

Safety data is available for 2 to 5 years on all 25 patients

** A grade 2 dysesthesia which began 47 days post-injection, but resolved by the Year 2 follow-up visit*

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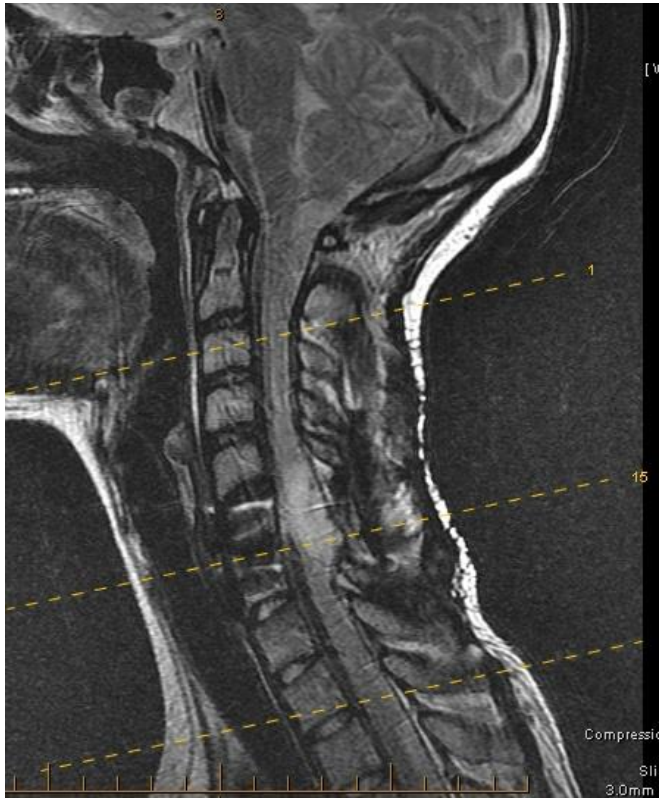
OPC1 Prevention of Cavitation

- **Cystic cavitation (syringomyelia) occurs in ~80% of SCI cases**
- **96% (24/25) of OPC1 patients had serial MRI scans that indicated <u>no sign</u> of a lesion cavity at 12 months (or 24 months for 22 scans available)**
- **MRI results suggest formation of a tissue matrix at the injury, indicating OPC1 cells have durably engrafted and helped <u>prevent syringomyelia</u>**



Weighted sagittal MRI

12- and 24-Month MRI Scans Indicate Durable Engraftment of OPC1

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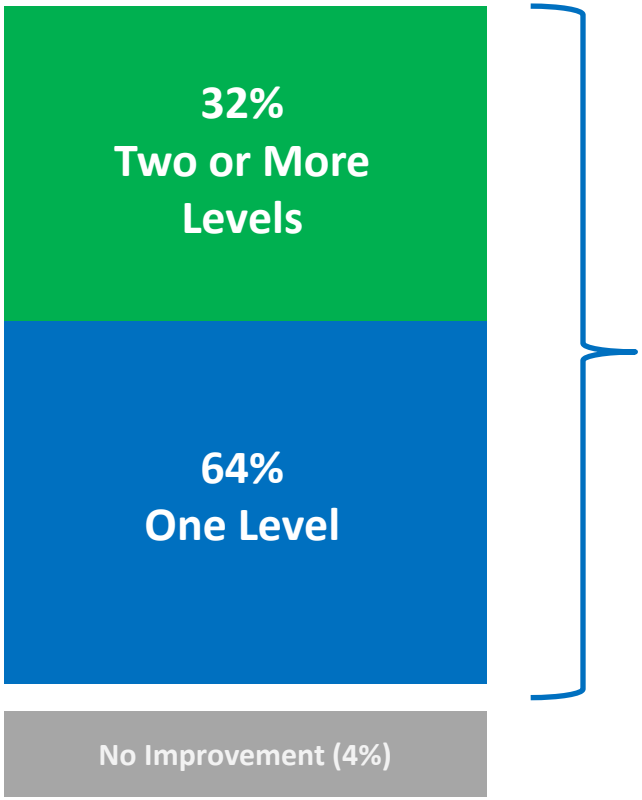
OPC1 - Motor Function Gains

22 Patients at 12 months



96%
of Subjects
Reported
Improved Motor
Function

N=22 because 3 patients from Cohort 1 received a sub-clinical "safety" dose of only 2M cells (the clinical dose is 10-20M cells)

Real-World Benefit from a 2 Motor Level Improvement

Motor level gains translate into clinically meaningful improvements in self-care and reductions in cost of care

32% had +2 Level Improvement

Function	Cervical Injury Level				
	C1-C3	*C4*	*C5*	*C6*	*C7-C8*
Bowel					
Bladder					
Bed Mobility					
Transfers					
Pressure Relief					
Eating					
Dressing					
Grooming					
Bathing					
Wheelchair					
Car transport					
Daily Home Care	24 hr attendant	18-24 hr attendant	6-12 hr assistance	4 hr housework	1 hr housework

Total Assist **Partial Assist** **Independent**

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

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OPC1 Clinical Trial - Analysis of Patients with Least UEMS Recovery

C4 or cord compressions occurred in 5 of the 7 worst patient outcomes and both issues can be addressed in the next trial

Subject	UEMS Change at 12 mo.	Cord Compression After OPC1 Injection?	NLI Baseline	Baseline AIS	Cohort	Dose	Age	Injection Days Post Injury
2207	7	N	C4	B	5	20 M	62	37
2203	6	N	C6	A	3	20 M	45	31
2105	6	N	C4	A	3	10 M	19	20
2004	5	N	C6	B	4	10 M	21	25
2007	4	N	C4	B	4	10 M	55	38
2307	4	Y	C5	B	5	10 M	19	38
2303	3	Y	C6	B	4	10 M	22	35

- **Two patients had cord compression after OPC1 injection (Day 30 and Day 7)**
- **Three patients had a C4 (highest/most severe) injury level at baseline**
- **Patient 2105 had a failed graft, believed related to a hematoma in the spinal cord at baseline**

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New Spinal Cord Delivery System – Clinical Testing in 2022

- **Better stability and control**
  - Eliminates motion between platform/XYZ manipulator/needle
- **Enhanced usability and safety: no cessation of ventilation**
  - Attaches directly to the patient, compatible with breathing motion
- **Improved user experience**
  - Smaller and fewer components
  - Single hand operation
- **Animal testing ongoing**
- **Device trial in sub-acute <u>and</u> chronic patients expected to begin 1H 2022**

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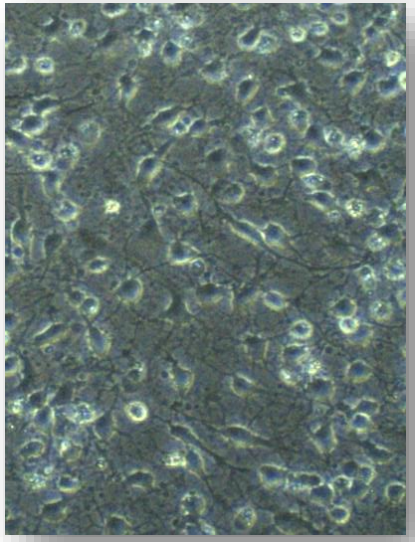
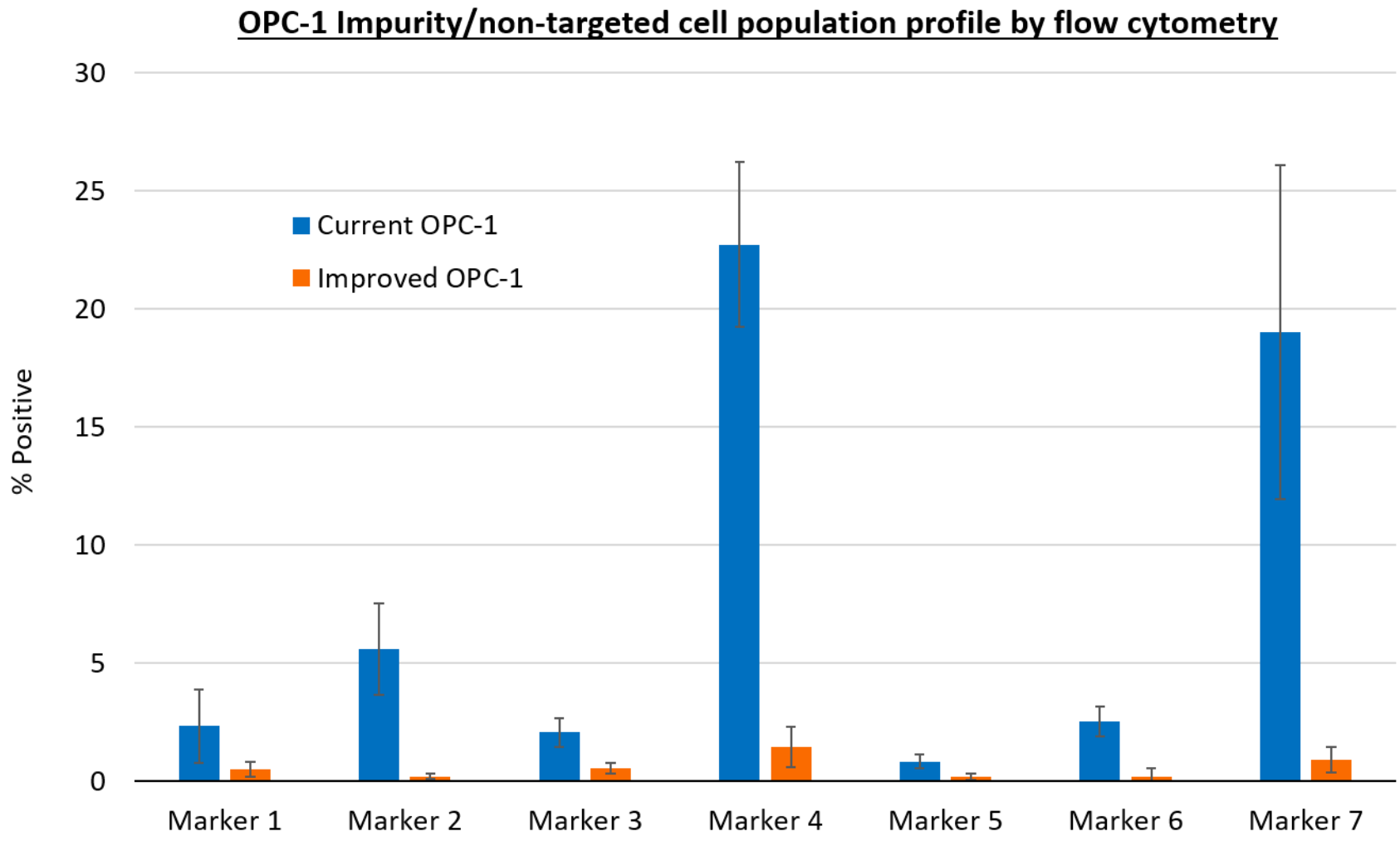
OPC1 Manufacturing and Quality Improvements

Lineage has made major improvements to the original OPC1 cells



- **Developed a new ready-to-inject formulation**
- **Eliminated dose preparation steps**
- **Up to 20-fold increase in production scale**
- **Significant reduction in impurities**
- **No reduction in functional activity**
- **12 new analytical and functional methods developed**
- **Elimination of all animal-based production reagents**
- **Patent applications on the process and product, pending allowance, will have expiration dates of 2039 and 2040**

OPC1 Manufacturing Improvements: Lower Impurities



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OPC1 Program – Key Takeaways

- **95% of patients exhibited UE motor recovery at 12 months (at least 1 motor level on 1 side)**
- **Syringomyelia events reduced to 4% (~80% expected)**
- **96% durable engraftment**
- **Excellent overall safety profile (5 years and continues)**
- **Can enrich for better-performing population in next trial**
- **Greatly improved purity and production scale of clinical material**
- **Superior delivery device entering clinical testing (safety trial can include chronic patients)**
- **Planning underway for a randomized, controlled clinical trial**

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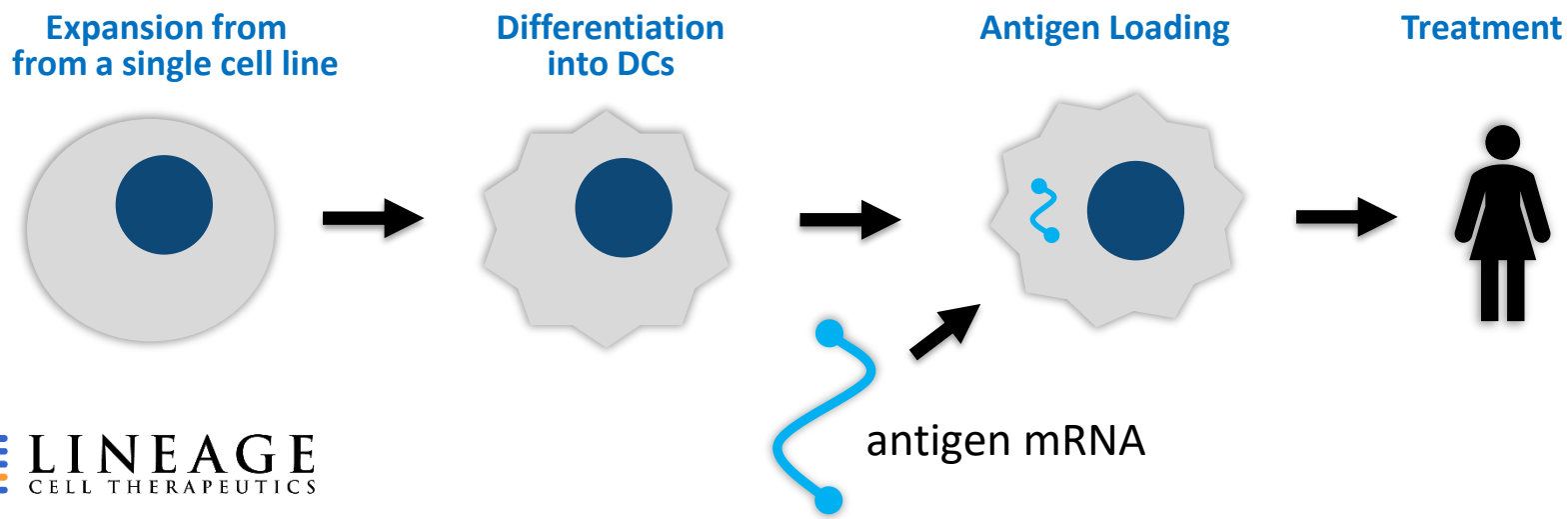
Immunotherapy is "poised to revolutionize treatment for all types of cancer"

Source: cancerresearch.org

VAC: A Cell Therapy Platform for Cancer and Infectious Diseases

The VAC Platform: On Demand Cell Therapy for Cancer

- **The VAC platform consists of allogeneic ("off the shelf") dendritic cells (DCs)**
  - **Eliminates the delay between diagnosis and treatment, a major deficiency of autologous approaches.**
- **DCs are manufactured and loaded with either a tumor antigen (to treat cancer) or a viral antigen (as a vaccine for infectious diseases)**
- **Antigen presentation to the patient's T cells creates a *targeted* and *robust* immune response (up to 3%), aiding tumor cell destruction or pathogen clearance**



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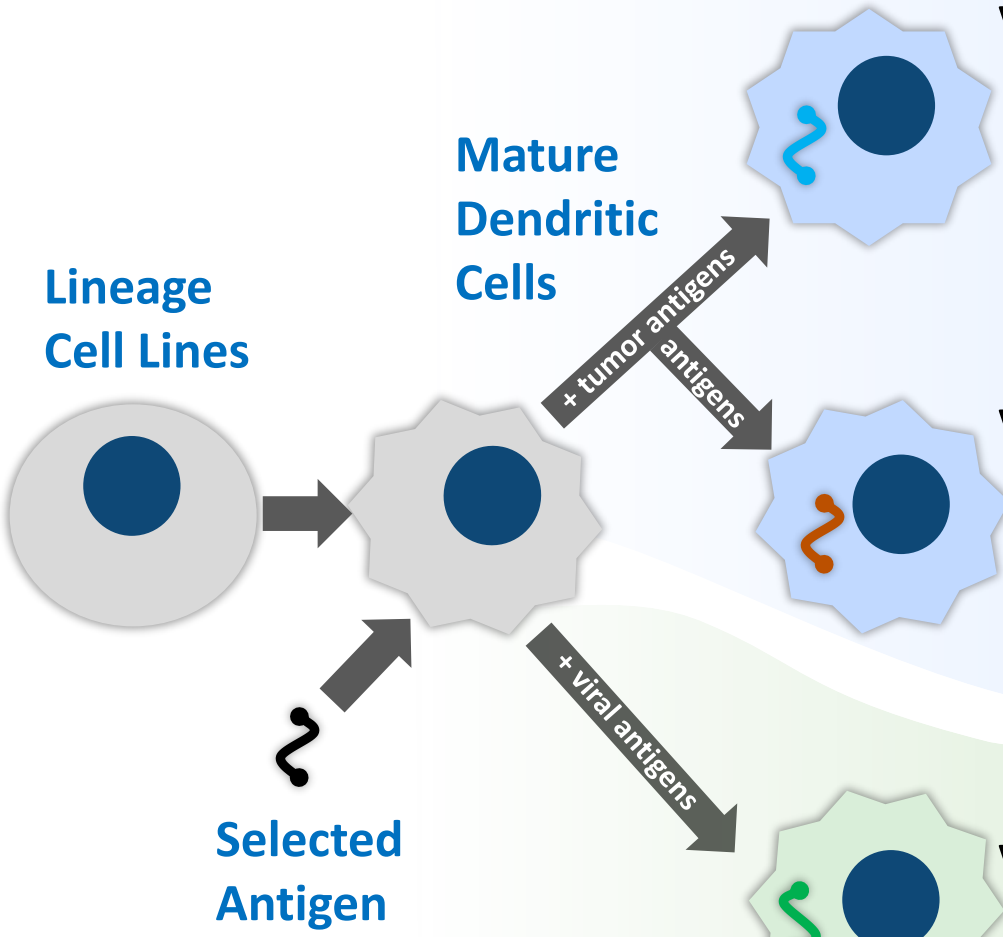
VAC – A Platform for Many Product Candidates



VAC1 and VAC2 Highlights

- Positive phase 1 data in AML
- Ongoing phase 1 trial in lung cancer (NSCLC)
- Cancer Research UK alliance
- High T cell responses measured

VAC3, VAC4, VAC5…Opportunities

- Partnerships based on new products
- Retain highest value candidates
- Currently evaluating new antigens

VAC-Infectious Diseases

- Designed to provide long-term protection via memory T cells
- Leverages VAC clinical data

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VAC2 - Phase 1 Clinical Trial

Study is Ongoing, Being Conducted by Cancer Research UK

- **Enrollment ongoing in NSCLC (7 patients treated to date)**
- **VAC2 has been well tolerated in all patients; no treatment delays due to adverse events attributable to VAC2**
- **Encouraging Phase 1 data**
  - Induction of durable, antigen-specific linked T cell help
  - T cell induction 40-400 times higher than with DNA/RNA vaccines
  - Well-tolerated: Injection site reactions, flu-like symptoms (all grade 1 or 2)
  - Adverse events suggest induction of an adaptive immune response
- **Safety and mechanistic (immunogenicity) data from CRUK-led trial supports advancing VAC2 internally**
  - Planning to submit IND for next trial upon completion of ongoing CRUK study

VAC Platform Next Steps

Upcoming Events and Key Considerations:

- **Complete enrollment in ongoing clinical trial (1 patient remaining)**
- **Identify improvements to the manufacturing process (at Lineage)**
- **Design new products (VAC3, 4, 5, 6…) with newly discovered antigens**
  - Opportunities to partner with novel antigen sources (companies, academics)
- **Seek partnership opportunities for expansion of the platform**
  - First strategic alliance with Immunomic Therapeutics announced April 2021

Our Goal is to Provide Life-Changing Cell Therapies to Patients

Lineage Cell Therapeutics: Bringing the Promises of Cell Therapy into Clinical Reality

Clinical-stage programs with billion-dollar potential and partnership opportunities

World class in-house process development and GMP manufacturing

One of the largest patent portfolios in cell therapy

Multiple validating corporate partnerships

Leader in the field of regenerative medicine

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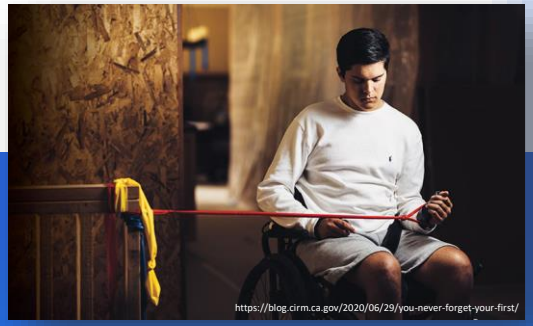
The Patients Are Our Inspiration.
View their stories at **lineagecell.com/media/#patients**

OPC1 SCiStar Study Participants

CIRM
CALIFORNIA'S STEM CELL AGENCY

Lucas Lindner
"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."

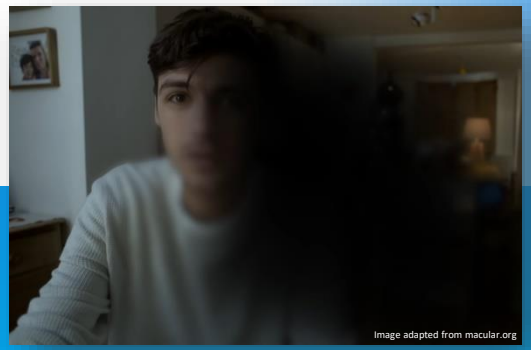
Kris Boesen
"I couldn't drink, couldn't feed myself, couldn't text or pretty much do anything, I was basically just existing. I wasn't living my life, I was existing."



Jake Javier
"Even though it's a completely different perspective, I can still lead that way. I can just try to be the best I can and to persevere the best I can."
Diablo Magazine, Feb. 16, 2017

The Millions Worldwide Suffering from Dry AMD Vision Loss

"Macular degeneration is a very frustrating condition which can greatly affect your day-to-day life."
- Macular Society



Courtesy of CIRM, American Macular Degeneration Foundation, and Macular Society