# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

#### FORM 8-K

**CURRENT REPORT** Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 6, 2021

# Lineage Cell Therapeutics, Inc.

(Exact name of registrant as specified in charter)

**California** (State or other jurisdiction

of incorporation)

**001-12830** (Commission File Number) 94-3127919 (IRS Employer Identification No.)

2173 Salk Avenue, Suite 200 Carlsbad, California (Address of principal executive offices)

**92008** (Zip Code)

(442) 287-8990

Registrant's telephone number, including area code

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered	
Common stock	LCTX	NYSE American	

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

#### Item 7.01. Regulation FD Disclosure.

Lineage Cell Therapeutics, Inc. ("*Lineage*") will participate in virtual meetings with analysts and investors beginning January 6, 2021 and through the conclusion of the J.P. Morgan 39th Annual Healthcare Conference on January 14, 2021. During those meetings, Lineage will use a presentation handout, which is furnished as Exhibit 99.1 and is incorporated herein by reference. The presentation handout will also be made available in the "Investors" section of Lineage's website, located at investor.lineagecell.com.

Lineage undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time through the filing of other reports or documents with the Securities Exchange Commission, through press releases, or through other public disclosure, including in the "Investors" section of Lineage's website. Lineage routinely uses its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	January 2021 corporate presentation handout
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

#### Lineage Cell Therapeutics, Inc.

Date: January 6, 2021

By: /s/ Chase C. Leavitt

Name: Chase C. Leavitt Title: General Counsel and Corporate Secretary



January 5, 2021

This presentation is for informational purposes only and is not an offer to sell or a solicitation of an offer to buy any securities of Lineage Cell Therapeutics, Inc. ("Lineage"). This presentation includes certain information obtained from trade and statistical services, third-party publications, and other sources. Lineage has not independently verified such information and there can be no assurance as to its accuracy.

All statements in this presentation, other than statements of historical fact, are forward-looking statements within the meaning of federal securities laws. In some cases, you can identify forward-looking statements by terms such as "may," "will," "expect," "plan," "anticipate," "strategy," "designed," "could," "intend," "believe," "estimate," "target," or "potential" and other similar expressions, or the negative of these terms. Forward-looking statements involve risks, uncertainties and assumptions that may cause Lineage's actual results, performance, or achievements to be materially different from those expressed or implied by the forward-looking statements in this presentation, including risks and uncertainties inherent in Lineage's business and other risks described 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 are expressly qualified in their entirety by these cautionary statements. Further information regarding these and other risks is included under the heading "Risk Factors" in Lineage's periodic reports filed with the SEC, including Lineage's Annual Report on Form 10-K filed with the SEC on March 12, 2020 and its other reports, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Lineage undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.





#### **Management Biographies**



BRIAN CULLEY, CEO



BRANDI ROBERTS, CFO

Mr. Culley joined Lineage as CEO in September 2018. Prior to joining Lineage, Mr. Culley served from August 2017 to September 17, 2018 as Interim Chief Executive Officer at Artemis Therapeutics, Inc., where he was responsible for the management of the company. Mr. Culley previously served as Chief Executive Officer of Mast Therapeutics, Inc. ("Mast"), from February 2010, and was also a member of its Board of Directors from December 2011, until Mast's merger with Savara, Inc. in April 2017. Mr. Culley served from January 2007 to February 2010 as Mast's Chief Business Officer and Senior Vice President, from February 2006 to January 2007 as Mast's Senior Vice President, Business Development. From 2002 until 2004, Mr. Culley was Director of Business Development and Marketing for Immusol, Inc. From 1999 until 2000, he worked at the University of California, San Diego (UCSD) Department of Technology Transfer & Intellectual Property Services and from 1996 to 1999 he conducted drug development research for Neurorine Biosciences, Inc. Mr. Culley has more than 25 years of business and scientific experience in the life sciences industry. He received a B.S. in biology from Boston College, a masters in biochemistry and molecular biology from the University of California, Santa Barbara, and an M.B.A. from The Johnson School of Business at Cornell University.

Ms. Roberts joined Lineage as CFO in January 2019. Prior to joining Lineage, Ms. Roberts served from August 2017 to January 4, 2019 as Chief Financial Officer at REVA Medical, Inc. Ms. Roberts previously served as Chief Financial Officer at Mast Therapeutics, Inc., a publicly traded US-based biopharmaceutical company, from January 2013 to April 2017, having served as the Company's Senior Vice President, Finance from March 2011 to January 2013. Previously, she held senior positions at Alphatec Spine, Artes Medical, Stratagene and Pfizer. Ms. Roberts brings more than 23 years of public accounting and finance experience, including 20 years at publicly traded pharmaceutical, medical technology, and life science companies to her position. Ms. Roberts is a certified public accountant with the State of California and received her B.S. in Business Administration from the University of Arizona and her M.B.A. from the University of San Diego. Ms. Roberts serves on the board of Temple Therapeutics BV. She also currently serves as Chair of the Association of Bioscience Financial Officers.



# Lineage Cell Therapeutics – Investor's Overview

Innovative Approach	- Transplanting "off the shelf" cells to treat serious medical conditions
Unique Advantage	<ul> <li>World-class manufacturing and IP; can manufacture an unlimited supply of specialized cell types from established pluripotent cell lines</li> </ul>
Three Clinical Stage Programs	<ul> <li>OpRegen: Phase 1/2a in Dry Age-Related Macular Degeneration with GA</li> <li>OPC1: Phase 1/2a in Cervical Spinal Cord Injury</li> <li>VAC2: Phase 1 in oncology (non-small cell lung cancer + platform)</li> </ul>
Compelling Data	<ul> <li>First-ever report of retinal tissue <u>restoration</u> in a dry AMD patient</li> <li>One-third of spinal cord patients gained <u>2 levels</u> of motor function</li> <li>Potent <u>induction of immune responses</u> observed in cancer patients</li> </ul>
Market Opportunities	- Billion-dollar commercial potential for each program
Near-Team Clinical News	- 3- and 6-month data from dry AMD program, expected Q1 and Q2 - Completion of enrollment in Phase 1 lung cancer trial, expected Q1
Strong Financial Position	- Cash and marketable securities of \$38 million as of September 30, 2020
Market Capitalization	~\$264 million as of December 31, 2020







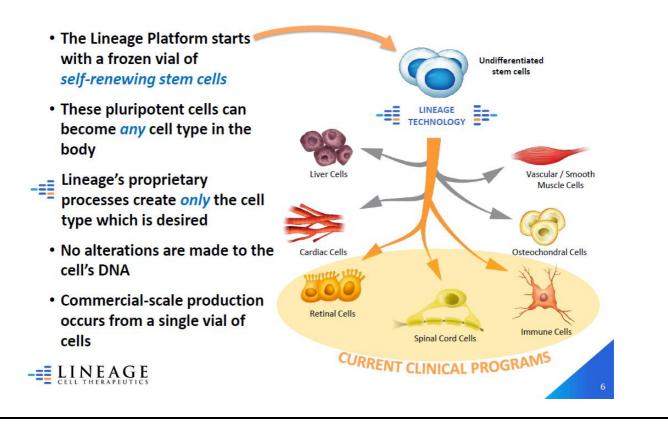


"We aim to pioneer a new branch of medicine, based on transplanting specific cell types into the body"

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# **Technology Overview**

# Lineage Technology Platform – Allogeneic Cell Transplants



#### Competitive Advantage: In-House Manufacturing and Know-How

# Lineage's competitive advantage is the *differentiation* of an *unlimited* supply of pluripotent stem cells into specialized cell types

#### Capabilities

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



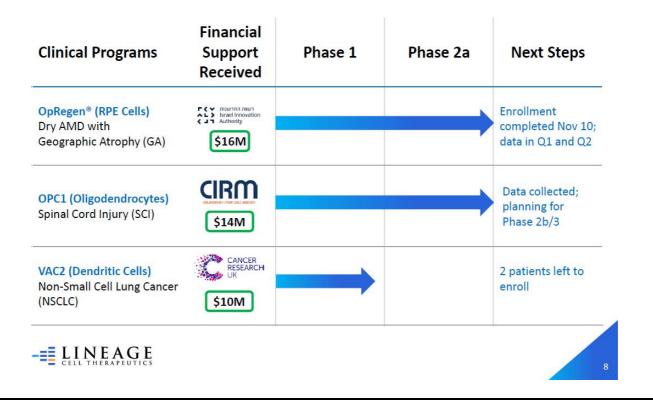
Cell Cure Neurosciences (Subsidiary)

#### Backed by hundreds of cell therapy-related patents





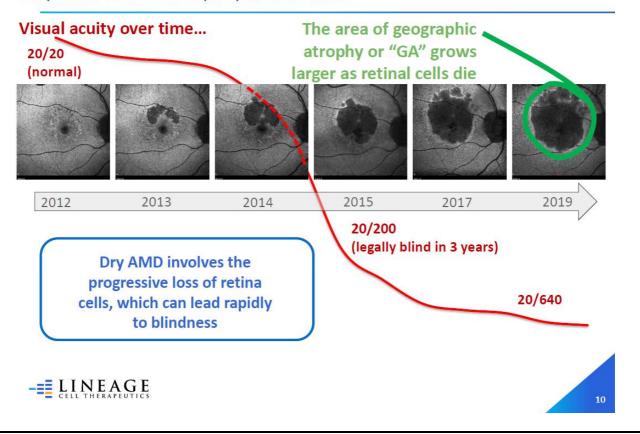
# Pipeline and Validating Partnerships







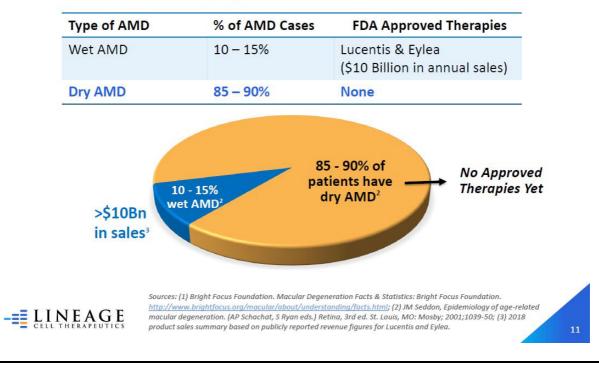
# **OpRegen**<sup>®</sup>: **RPE** Cell Transplants to Treat Dry AMD



### Dry AMD Can Lead Rapidly to Blindness

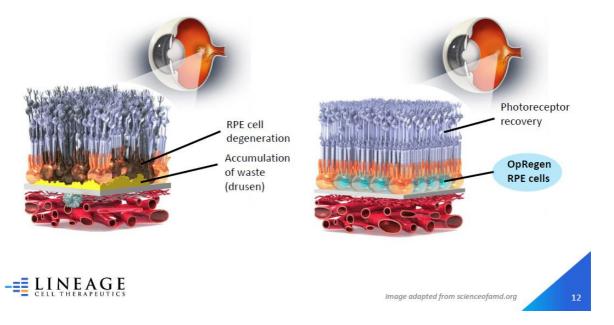
#### Multi-Billion Dollar Market Opportunity in the U.S.

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

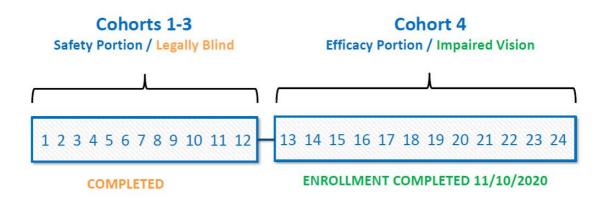


# Lineage Approach – OpRegen, an RPE Cell Transplant

- Dry AMD involves the loss of retina cells, creating an area of geographic atrophy (GA), which causes impaired vision and blindness
- OpRegen is an injection of **RPE cells** directly to the retina, to replace lost retinal cells and preserve or improve vision



## Ongoing Phase 1/2a Clinical Trial of OpRegen for Dry AMD







#### Promising Results (As of AAO 2020 Update)

- The transplanted OpRegen cells have been well tolerated with no cases of rejection
- Cohort 4 patients (the intended commercial population) have better vision at 9 & 12 months, with improvements lasting >24 months in some patients
- A trend towards slower GA growth was observed in first 6 Cohort 4 patients, also maintained for as long as 24 months in some patients
- Encouraging findings across unrelated assessments; various patients have exhibited evidence for one or more of:
  - 1. Reduced growth of geographic atrophy
  - 2. Improved visual acuity
  - 3. Improved reading speed
  - 4. Improved retina structure
  - 5. Reductions in waste material
  - 6. Stable engraftment of cells (4+ years)
  - 7. Restoration of retinal tissue maintained to 23 months (continuing to monitor)



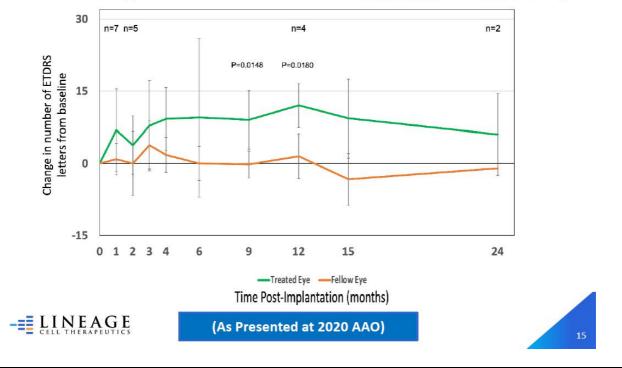
Data presented at 2020 ARVO Virtual Meeting

FIRST KNOWN

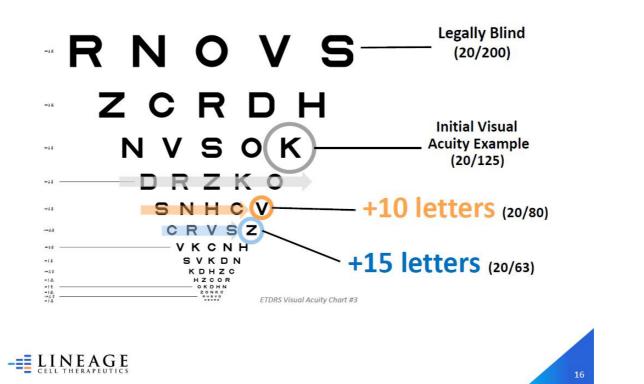
**REPORT!** 

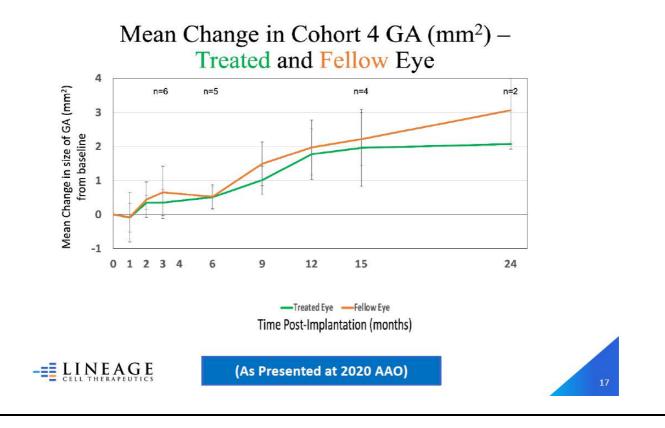
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# Mean Change in Cohort 4 BCVA – Treated & Fellow Eye



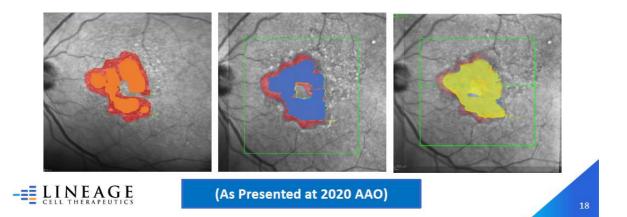
Real-World "Letters of Improvement"





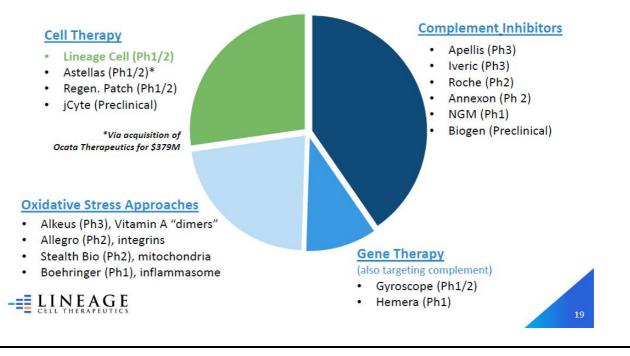
Date	Time in Study	Colored area on Figure below	Area mm <sup>2</sup> (SQRT)	Changes in rate of progression from previous	Changes in rate of progression from baseline
May 2017	Minus 1 year	Orange	4.21 mm <sup>2</sup> (2.05)	N/A	N/A
July 2018	Baseline	Red	7.90 mm <sup>2</sup> (2.8)	+ 0.64 mm sqrt/yr	N/A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

# Retinal Restoration – *Smaller* Area of GA, Maintained for 2 Years



#### Dry AMD Competitive Landscape

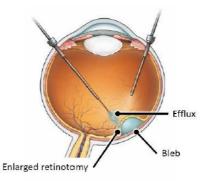
<u>Only</u> cell therapy has the potential to restore tissue with infrequent dosing <u>Only</u> Lineage has shown evidence of retinal restoration <u>Only</u> Lineage has access to the Gyroscope delivery system to deliver cells



#### Proprietary Delivery System – The Gyroscope SDS

#### Lineage has an <u>exclusive</u> option to a delivery device which overcomes issues with the traditional method of delivering cells to the retina

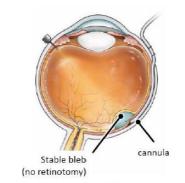
#### Traditional Method (safety issues)



- The traditional method punctures the retina; cells then efflux (pass) into the vitreous cavity, causing adverse events (ERMs)
- ERMs were observed in 14 out of 17 patients



#### Gyroscope SDS (Lineage method)



- With the Gyroscope SDS, no retinotomy is performed, providing better dose control
- No patients formed an ERM after using the Gyroscope SDS (n=7, p=<0.001 versus traditional method)

Images courtesy of Gyroscope Therapeutics Limited, all rights reserved Lineage has an exclusive option on the use of Gyroscope SDS to deliver cells for dry AMD

#### Commercial-Scale Manufacturing Capabilities

- OpRegen consists of >99% pure RPE cells
  - Uses NIH-approved line was established >20 years ago
  - Extensive characterization and karyotyping performed on each batch
  - No genetic modifications are made to the cells
- Immediate-use "thaw and inject" formulation
  - No dose preparation is required
  - From frozen cells to injection device in 5 minutes
- Current production scale is 5 billion cells per 3-liter bioreactor
  - Equal to 2,500 clinical doses/batch
  - Further scale-up can be performed in larger or parallel reactors





OpRegen has been designed to capture a multi-billion dollar opportunity:

- Transplanting RPE cells may provide benefits other approaches cannot
- Market opportunity is not limited to monogenic deficiencies (e.g. gene therapy)
- Treatment to date has been well-tolerated
- Some patients have exhibited clinically meaningful improvements in clinicallyrelevant metrics such as visual acuity and reading speed
- Potential for recurring revenues (with multiple treatments years apart)
- May have application in other retina diseases (Stargardt's Disease)
- Issued patents cover aspects of production, characterization, and formulation
- Fast Track designation from FDA
- Exclusive rights to unique delivery device
- Opportunities for strategic partnerships for late-stage development









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

Source: christopherreeve.org

**OPC1: A Cell Therapy** for Spinal Cord Injuries

# Lucas' Story



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.

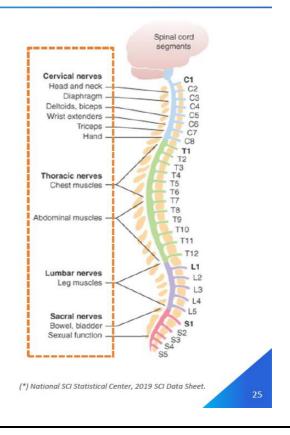




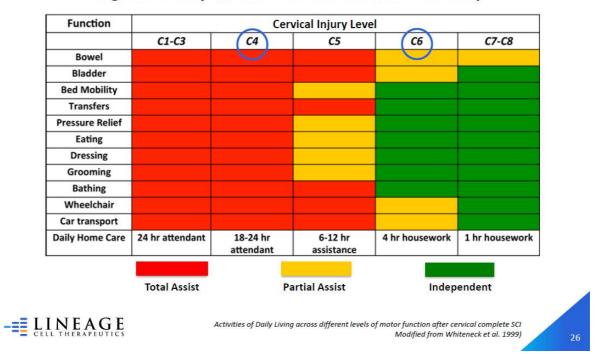
#### About Spinal Cord Injury

- Loss of movement is the primary feature of a spinal cord injury
- The goal of treatment is to provide additional upper extremity function (limb, hand & fingers)
- Greater mobility leads to improved quality of life and independence for patients
- Approx 18,000 persons per year in the US (Orphan Drug Designation received)
- Individual cost of care can reach as high as \$5M dollars



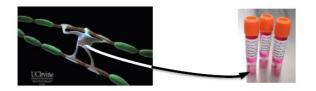






#### Higher-level injuries are associated with less mobility

Healthy oligodendrocytes, which support and myelinate neurons, can be damaged and lost due to inflammatory response following an injury



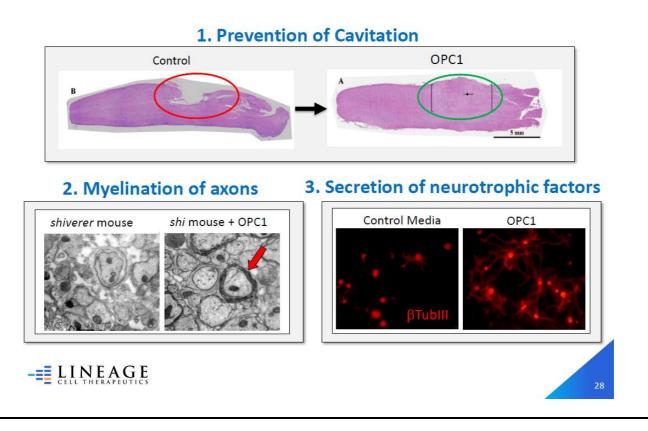
#### OPC1 is a <u>cellular therapy</u> comprised of oligodendrocyte progenitor cells (OPCs) which are derived from a pluripotent cell line and injected into the patient's spinal cord

#### Demonstrated OPC1 activities:

- Remyelinate axons
- Tissue remodeling: neovascularization, cavitation prevention
- Promote neurite growth
- Improve motor function



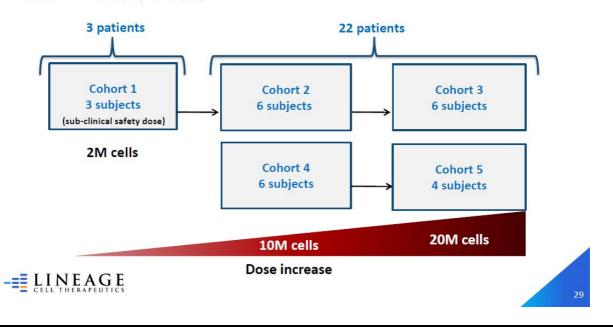




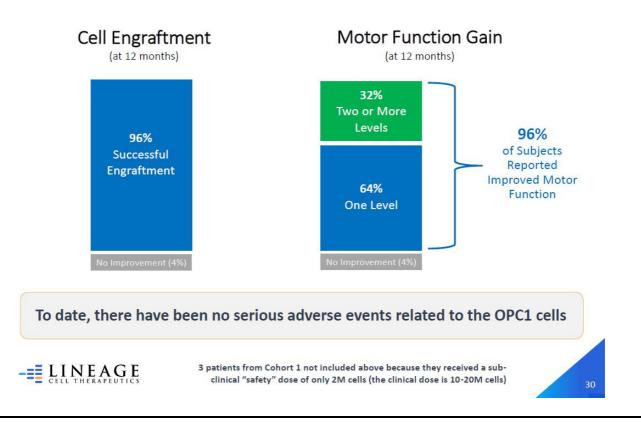
#### Clinical Trial Design (enrollment complete)

- Open Label (n=25)
- Primary Assessment: Safety
- Secondary Assessment: Neurological Function (ISNCSCI)
- AIS-A and AIS-B Enrolled
- Exploratory Functional Assessments: (SCIM, GRASSP)
- Dosed 21-42 days post injury

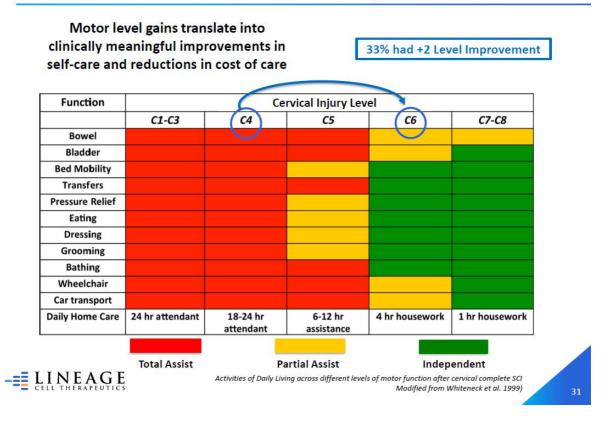
• Traumatic cervical SCI (C4-C7)



## Clinical Trial Results - Safety and Efficacy in 22 Patients



# Real-World Benefit from a 2 Motor Level Improvement



- Promising overall safety profile (21 subjects evaluated)
  - No evidence of adverse changes via MRI
  - No unexpected serious adverse events related to the OPC1 cells
  - No study subjects had worsening of neurological function
- Motor Level Improvements Persist and Improve
  - Cohort 1 subjects continue to be stable 3-4 years after treatment
  - 5 of 6 subjects in cohort 2 achieved at least 2 motor levels of improvement
  - 1 subject in cohort 2 achieved <u>3 motor levels of improvement</u>; maintained at 3 years
- Results support further evaluation in a randomized, controlled study





#### OPC1 Manufacturing Update (December 8, 2020)

#### Major improvements in production and quality of OPC1 product

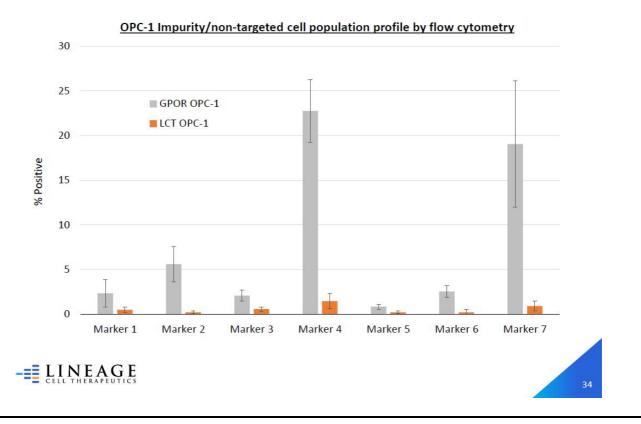
- A new ready-to-inject formulation
- Elimination of dose preparation
- A 10 to 20-fold increase in production scale
- A significant reduction in product impurities (next slide)
- Improvements in functional activity
- Development of 12 new analytical and functional methods
- Elimination of all animal-based production reagents
- Patent applications recently filed on the process and product, if allowed, are expected to have expiration dates in 2039 and 2040











#### **Key Considerations:**

- Compelling clinical data supports later-stage comparative clinical trial
- Manufacturing deficiencies of prior sponsor have been addressed
- Delivery device enhancements can enable a greater number of sites
- Planning to meet with FDA to discuss manufacturing improvements and device evaluation
- Will begin considering regional and/or global partnership opportunities and external grant funding (CIRM and other organizations)





# -= LINEAGE



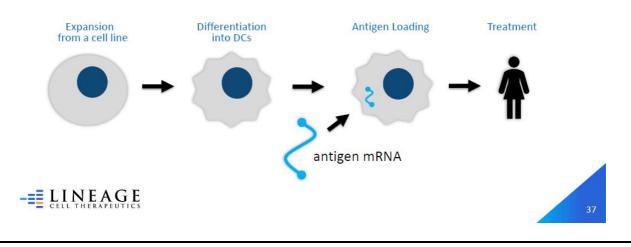
Immunotherapy is "poised to revolutionize treatment for all types of cancer"

Source: cancerresearch.org

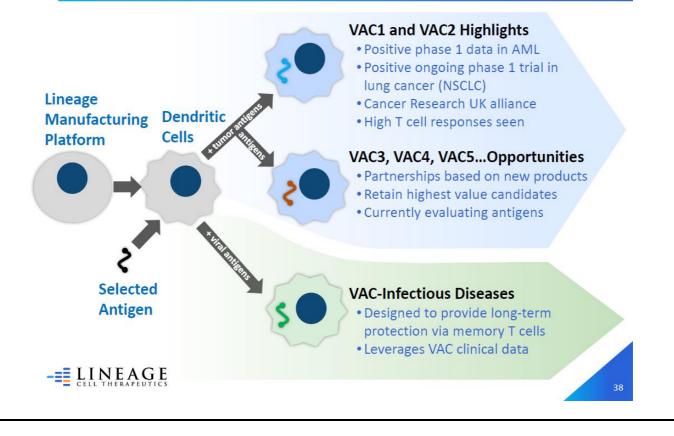
VAC: A Cell Therapy Platform for Cancer and Infectious Diseases

#### The VAC Platform: Allogeneic Solutions for Autologous Problems

- The VAC platform consists of large-scale "off the shelf" production of mature immune cells called dendritic cells (DCs)
- 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 viral clearance



#### VAC Development – Many Programs from a Single Platform



**Upcoming Events and Key Considerations:** 

- Complete dosing in ongoing clinical trial (2 patients remain)
- Evaluate options for VAC2 with a checkpoint inhibitor
- Design new products (i.e. VAC3, 4, 5, 6...) with newly discovered antigens
- Identify potential partnership and grant opportunities for more rapid expansion of the VAC platform





# Upcoming Milestones

PROGRAM	TIMING	INITIATIVES
OpRegen	Q1 2021	Present interim OpRegen data (3-month Cohort 4 update)
	Q2 2021	Present interim OpRegen data (6-month Cohort 4 update, ARVO)
	2H 2021	Planning discussions with the FDA on future clinical development
	Ongoing	Evaluate OpRegen partnership opportunities
VAC	Q1 2021	Complete dosing in ongoing clinical trial in NSCLC (n=8; 2 remain)
	Q3 2021	Report Phase 1 NSCLC data
	Ongoing	Evaluate new product candidates with additional tumor antigens/neoantigens
OPC1	Q1 2021	Host Therapeutic Expert Call / R&D Day
	1H 2021	Complete process development to support late-stage clinical trial
	1H 2021	Meet with the FDA to discuss manufacturing improvements and device evaluation
	Ongoing	Evaluate delivery device options to access more clinical sites
	Ongoing	Consider regional and/or global partnership opportunities





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

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



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

#### **OPC1 SCiStar Study Participants**

# **CIRM**



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." Diable 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

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