

# Lineage Cell Therapeutics Proudly Supports Patients' Access to Innovative Cell Therapy Treatments and Research Through Passage of Proposition 14

November 13, 2020

### Voters Authorize California Institute for Regenerative Medicine to Fund \$5.5 Billion in Grants for Stem Cell Research and Development

CARLSBAD, Calif.--(BUSINESS WIRE)--Nov. 13, 2020-- Lineage Cell Therapeutics. Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs, strongly endorses the recent passing of Proposition 14 in California. This bill will enhance patients' access to groundbreaking stem cell therapy treatments by authorizing the California Institute for Regenerative Medicine (CIRM) the ability to fund up to \$5.5 billion in grants to support therapeutic development, medical research, and facilities based on stem cell technologies. This initiative builds upon the success of Proposition 71, which issued approximately \$3 billion for the funding of stem cell research and led to important medical advances, including functional cures in some patients receiving cell therapy treatments. The development of Lineage's OPC1 oligodendrocyte progenitor cell therapy for the treatment of acute spinal cord injury (SCI), was one of the first clinical trials supported by CIRM and has showed durable and encouraging results in some patients.

"At Lineage, the patients and their families inspire us to advance cell therapy products and this recent approval of Proposition 14 ensures that access to cutting edge cell-based therapies can continue from companies like ours," stated Brian M. Culley, Lineage CEO. "Cell therapy has the ability to make a profound impact on millions of lives and the passage of Proposition 14 reflects California's serious commitment to supporting innovative local companies through the expensive and time-consuming process required to discover and test new cell-based therapies and will drive further innovation in stem cell development and research. Of note, our clinical study of OPC1 for the treatment of acute spinal cord injury was one of the first cell therapy clinical trials supported by CIRM under Prop 71. It was tremendously meaningful for some of our patients' success stories to be featured in the Prop 14 campaign this year, along with others who have experienced life-changing benefits from stem cell therapy innovation in California. We are extremely thankful to CIRM for their partnership and valuable contributions, not only to Lineage, but also for other companies working in this exciting and rapidly growing field. We believe that all three of our clinical-stage programs could be considered for future grant funding under this new initiative."

#### **About OPC1**

OPC1 is an oligodendrocyte progenitor cell (OPC) transplant therapy designed to provide clinically meaningful improvements to motor recovery in individuals with acute spinal cord injuries (SCI). OPCs are naturally occurring precursors to the cells which provide electrical insulation for nerve axons in the form of a myelin sheath. SCI occurs when the spinal cord is subjected to a severe crush or contusion injury and typically results in severe functional impairment, including limb paralysis, aberrant pain signaling, and loss of bladder control and other body functions. There are approximately 18,000 new spinal cord injuries annually in the U.S. and there currently are no FDA-approved drugs specifically for the treatment of SCI. The OPC1 program has been partially funded by a \$14.3 million grant from the California Institute for Regenerative Medicine. OPC1 has received Regenerative Medicine Advanced Therapy (RMAT) designation and Orphan Drug designation from the U.S. Food and Drug Administration (FDA).

## **About the OPC1 Clinical Study**

The <u>SCiStar Study</u> of OPC1 is an open-label, 25-patient, single-arm trial testing three sequential escalating doses of OPC1 which was administered 21 to 42 days post-injury, at up to 20 million OPC1 cells in patients with subacute motor complete (AIS-A or AIS-B) cervical (C-4 to C-7) acute spinal cord injuries (SCI). These individuals had experienced severe paralysis of the upper and lower limbs. The primary endpoint in the SCiStar study was safety as assessed by the frequency and severity of adverse events related to OPC1, the injection procedure, and immunosuppression with short-term, low-dose tacrolimus. Secondary outcome measures included neurological functions measured by upper extremity motor scores (UEMS) and motor level on International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) examinations through 365 days post-treatment. Enrollment is complete in this study; patients will continue to be evaluated on a long-term basis.

# About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs. Lineage's programs are based on its robust proprietary cell-based therapy platform and associated in-house development and manufacturing capabilities. With this platform Lineage develops and manufactures specialized, terminally differentiated human cells from its pluripotent and progenitor cell starting materials. These differentiated cells are developed to either replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury or administered as a means of helping the body mount an effective immune response to cancer. Lineage's clinical programs are in markets with billion dollar opportunities and include three allogeneic ("off-the-shelf") product candidates: (i) OpRegen <sup>®</sup>, a retinal pigment epithelium transplant therapy in Phase 1/2a development for the treatment of dry age-related macular degeneration, a leading cause of blindness in the developed world; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; and (iii) VAC, an allogeneic dendritic cell therapy platform for immuno-oncology and infectious disease, currently in clinical development for the treatment of non-small cell lung cancer. For more information, please visit <a href="https://www.lineagecell.com">www.lineagecell.com</a> or follow the Company on Twitter <a href="https://www.lineagecell.com">@LineageCell</a>.

# Forward-Looking Statements

Lineage cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "contemplate," project," "target," "tend to," or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to Lineage's expected eligibility for grants. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Lineage's actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in

this press release, including risks and uncertainties inherent in Lineage's business and other risks in Lineage's filings with the Securities and Exchange Commission (the 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 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.

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