Lineage's OPC1 Cell Therapy for the Treatment of Spinal Cord Injury to Return to Clinical Testing

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- **RMAT Interaction with FDA Held to Propose Clinical Testing of a Novel Delivery Device for OPC1**
- **Safety Study Eligibility is Expected to Include Patients with Chronic Injury**
- **Late-Stage Clinical Study Continues to be Planned for 2022**

CARLSBAD, Calif.--(BUSINESS WIRE)--Jun. 22, 2021-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today provided an update on the clinical advancement of OPC1, its investigational allogeneic oligodendrocyte progenitor cell (OPC) transplant therapy for the treatment of spinal cord injury (SCI). Following feedback received from an interaction held with the U.S. Food and Drug Administration (FDA) last week under the FDA's Regenerative Medicine Advanced Therapy (RMAT) program, Lineage intends to submit an amendment to its Investigational New Drug application (IND) for OPC1 to support a Phase 1 clinical study to evaluate the safety and performance of Neurgain Technologies Inc.'s Parenchymal Spinal Delivery System ("Neurgain PSD system") to deliver OPC1 cells to the spinal cord. In February, the Company entered into an exclusive option and license agreement with Neurgain to evaluate its novel PSD system in both preclinical and clinical settings. The IND amendment is expected to be submitted to the FDA in the fourth quarter of 2021. The data from the Phase 1 clinical study is intended to validate the Neurgain PSD system for use in a late-stage clinical study, expected to begin in 2022 following the completion of the Phase 1 study.

"It is a privilege to report that our novel OPC1 program will be returning to clinical testing earlier than anticipated. There currently are few opportunities for SCI patients to participate in clinical trials, so we are excited to re-engage with these patients and their advocacy community as part of our efforts to improve outcomes for individuals with this debilitating condition, for which there are no FDA-approved treatments," stated Brian M. Culley, Lineage's CEO. "In the past 18 months, we have significantly increased the purity and production scale of the OPC1 cells utilized in a prior clinical study. This improved production process has been transferred to our in-house Current Good Manufacturing Practice (cGMP) suite and will support production of clinical study material for later-stage clinical work. In parallel, we are finalizing plans to test the safety of the Neurgain PSD system to deliver OPC1 in SCI patients. We believe this device can improve the ease and precision of delivering our cells to the spinal parenchyma. As an added benefit, based on feedback from the FDA, in addition to patients with subacute SCI, we anticipate that patients with chronic SCI also will be eligible for enrollment in this study. Gaining additional OPC1 safety and device performance data across a broader range of patients and injury types will be more informative to the program and support further product and device development. Our recent accomplishments in areas of production and delivery contributed real-world feasibility to the promising clinical results previously reported with this program, in which OPC1 demonstrated improvements to quality of life and motor function for certain SCI patients. Importantly, we are working to be in a position to initiate a late-stage clinical study in SCI next year."

The Neurgain PSD system has been designed to allow for the administration of cells to the spinal cord without stopping the patient's ventilator during the procedure. Elimination of the need to stop respiration during surgery is expected to reduce the complexity, risk, and variability of administering cells to the area of injury. The Neurgain PSD system has been designed to provide delivery of cells with accurate anatomical positioning and dosing, is more compact than existing devices and is attached directly to the patient during the procedure. This innovative delivery system is expected to provide a significant improvement in usability and provide more flexibility to the surgeon when compared to the methods and tools utilized to deliver OPC1 cells in the completed Phase 1/2a SCiStar study of OPC1 for the treatment of cervical SCI. Neurgain Technologies, Inc. is a medical device company that is developing technologies developed by neurosurgeons at the University of California San Diego.

Lineage plans to evaluate the safety and performance of the Neurgain PSD system to deliver OPC1 to the spinal cord in both the preclinical and clinical setting. If results of these studies are positive, Lineage may exercise its option to enter into a pre-negotiated license and commercialization agreement with Neurgain. Pursuant to that agreement, Lineage may integrate the Neurgain PSD system into a late-stage clinical trial and, if approved, commercial use of OPC1 for the treatment of patients with spinal cord injury. There currently are no FDA approved treatments for spinal cord injury.

About Spinal Cord Injuries
A spinal cord injury occurs when the spinal cord is subjected to a severe crush or contusion and frequently 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. The cost of a lifetime of care for a severe spinal cord injury can be as high as $5 million.

About OPC1
OPC1 is an oligodendrocyte progenitor cell (OPC) transplant therapy designed to provide clinically meaningful improvements in motor recovery in individuals with subacute spinal cord injuries. OPCs are naturally occurring precursors to the cells which provide electrical insulation for nerve axons in the form of a myelin sheath. While variability exists for the precise duration of each phase, subacute SCI generally refers to the phase that is three to six weeks post-injury and chronic SCI refers to the phase beginning after the subacute phase. The OPC1 program has been partially funded by a $14.3 million grant from the California Institute for Regenerative Medicine (CIRM). OPC1 has received Regenerative Medicine Advanced Therapy (RMAT) designation for its use in subacute cervical SCI and Orphan Drug designation from the FDA.

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 ®, 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 subacute spinal cord injuries; and (iii) VAC2, an allogeneic dendritic cell therapy produced from Lineage's VAC technology platform for immuno-oncology and infectious disease, currently in Phase 1 clinical development for the treatment of non-small cell lung cancer. For more information, please visit www.lineagecell.com or follow the Company on Twitter @LineageCell.

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," "can," "plan," "potential," "predict," "seek," "should," "would," "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 advancement of the clinical development of OPC1 to treat SCI, OPC1's potential to improve quality of life and/or motor function for patients with SCI, the potential benefits of using the Neurgain PSD system to deliver OPC1 for the treatment of SCI, OPC1's regulatory approval pathway, and Lineage's potential exclusive license and commercialization agreement with Neurgain. 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 (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 most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the SEC 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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