Lineage Cell Therapeutics Provides Update on SCiStar Clinical Study and OPC1 Spinal Cord Injury Program

November 15, 2019

- **OPC1 Overall Safety Profile Excellent with Motor Recovery Gains in Upper Extremities Maintained Through Year 2 Follow-Ups Available to Date**
- **OPC1 Manufacturing Fully Transferred to cGMP Facility; Improvements to Manufacturing Process Planned During 2020**
- **FDA Meeting to Discuss OPC1 Manufacturing and Clinical Development Planned for Mid-2020**

CARLSBAD, Calif.--(BUSINESS WIRE)--Nov. 15, 2019-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cellular therapies for unmet medical needs, today provided an update on OPC1, the Company's oligodendrocyte progenitor cell (OPC) therapy currently being tested in a Phase I/IIa clinical trial, the SCiStar Study, for the treatment of acute spinal cord injury (SCI). Lineage reported positive results from the ongoing SCiStar study of OPC1, where the overall safety profile of OPC1 has remained excellent with robust motor recovery in upper extremities maintained through Year 2 patient follow-ups available to date. Additionally, OPC1 manufacturing has been completely transferred to the Company's cGMP manufacturing facility in Israel and manufacturing process improvements are planned to continue throughout 2020. Moreover, Lineage intends to meet with the U.S. Food and Drug Administration (FDA) to discuss further development of the OPC1 program around the middle of 2020.

"We remain extremely excited about the potential for OPC1 to provide enhanced motor recovery to patients with spinal cord injuries. We are not aware of any other investigative therapy for SCI which has reported as encouraging clinical outcomes as OPC1, particularly with continued improvement beyond 1 year," stated Brian M. Culley, CEO of Lineage Cell Therapeutics. "Overall gains in motor function for the population assessed to date have continued, with Year 2 assessments measuring the same or higher than at Year 1. For example, 5 out of 6 Cohort 2 patients have recovered two or more motor levels on at least one side as of their Year 2 visit whereas 4 of 6 patients in this group had recovered two motor levels as of their Year 1 visit. To put these improvements into perspective, a one motor level gain means the ability to move one's arm, which contributes to the ability to feed and clothe oneself or lift and transfer oneself from a wheelchair. These are tremendously meaningful improvements to quality of life and independence. Just as importantly, the overall safety of OPC1 has remained excellent and has been maintained 2 years following administration, as measured by MRI's in patients who have had their Year 2 follow-up visits to date. We look forward to providing further updates on clinical data from SCiStar as patients continue to come in for their scheduled follow up visits."

SCiStar Study Clinical Update

- **Overall safety profile of OPC1 to date is excellent for Year 2 follow-ups available to date (21 patients)**

  - Magnetic resonance imaging (MRI) scans at 24 months post-injection of OPC1 have shown no evidence of adverse changes in any of the 21 SCiStar study patients treated with OPC1 who have had their Year 2 follow-up visits.
  - To date, there have been no unexpected serious adverse events (SAEs) related to the OPC1 cells in these patients, with no concerning safety issues noted.
  - No SCiStar patient had a decline in their motor function from their Year 1 to Year 2 visits.
  - No adverse findings were observed on follow-up MRI scans.

- **Motor level improvements**

  - For Cohort 1, even at a low dose of OPC1, patients continue to be stable 2-4 years out post treatment.
  - Five of six Cohort 2 patients achieved at least two motor levels of improvement over baseline on at least one side as of their 24-month follow-up visit.
  - In addition, one Cohort 2 patient achieved three motor levels of improvement on one side over baseline as of the patient's 24-month follow-up visit; improvement has been maintained through the patient's 36-month follow-up visit.
  - Improvements in upper extremity motor function are being measured using the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) scale, widely used to quantify functional status of patients with spinal cord injuries. Improvements in upper extremity motor function are the most desirable functional improvement target in the quadriplegic population, since even relatively modest changes can potentially have a significant impact on functional independence, quality of life, and cost of care.

- **Upper Extremity Motor Score (UEMS)**

  - Impressive improvements in UEMS scores for Cohort 2 patients was observed at 24 months, with three patients who have recovered back to a UEMS in the mid-to-high 40's. The maximum total UEMS is 50.
  - The UEMS is a linear scale used to quantify motor function at each of five upper extremity muscle groups driving arm and hand function; these scores are also used to determine "motor levels", which define the level within the cord above which a

patient has normal function.

OPC1 Clinical Program Update

- OPC1 manufacturing has now completely been transferred to the Company's cGMP manufacturing facility in Israel.
- Continued improvements to the manufacturing process are planned during 2020 and include enhancements to the production process to ensure robust, controlled and commercially viable scale, purity, and reproducibility of OPC1.
- A meeting with the FDA is planned around the middle of 2020 to discuss the Company's proposed manufacturing improvements and the further development of OPC1 to best set the program up for success moving forward.
- Concurrently, Lineage will work to expand its partnerships with spinal cord injury advocacy and support organizations to support their mission to accelerate stem cell treatments to patients with unmet medical needs and fast-track the development of the most promising stem cell technologies.

About the SCiStar Clinical Study

The SCiStar Study is an open-label, 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 25 patients with subacute motor complete (AIS-A or AIS-B) cervical (C-4 to C-7) acute spinal cord injuries (SCI). These individuals had essentially lost all movement below their injury site and experienced severe paralysis of the upper and lower limbs. AIS-A patients had lost all motor and sensory function below their injury site, while AIS-B patients had lost all motor function but may have retained some minimal sensory function below their injury site. 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 as measured by upper extremity motor scores and motor level on International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) examinations at 30, 60, 90, 180, 270, and 365 days after injection of OPC1.

About OPC1

OPC1 is an oligodendrocyte progenitor cell (OPC) therapy currently being tested in a Phase I/IIa clinical trial known as SCiStar for the treatment of acute 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. 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. The clinical development of 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 for the treatment of acute SCI and has been granted Orphan Drug designation from the U.S. Food and Drug Administration (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 proprietary cell-based therapy platform and associated 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 either to 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 assets include (i) OpRegen®, a retinal pigment epithelium transplant therapy in Phase I/IIa 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 I/IIa development for the treatment of acute spinal cord injuries; and (iii) VAC2, an allogeneic cancer immunotherapy of antigen-presenting dendritic cells currently in Phase I development for the treatment of non-small cell lung cancer. Lineage is also evaluating potential partnership opportunities for Renevia®, a facial aesthetics product that was recently granted a Conformité Européenne (CE) Mark. 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," "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 planned manufacturing process improvements and meetings with regulatory agencies. 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 14, 2019 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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