Lineage Enters Into Exclusive Agreement with Neurgain Technologies to Evaluate Novel Delivery System for OPC1 to Treat Spinal Cord Injury

February 8, 2021

- **Use of the Neurgain PDI system could support later-stage trials of OPC1 in cervical injury patients**
- **OPC1 Investor & Analyst Day planned for February 22, 2021**

CARLSBAD, Calif.--(BUSINESS WIRE)--Feb. 8, 2021-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today announced that it has entered into an exclusive option and license agreement with Neurgain Technologies, Inc. ("Neurgain"), a medical device company that is commercializing technology developed by neurosurgeons at the University of California San Diego ("UC San Diego"). Under the terms of the agreement, Lineage and Neurgain will collaborate on the clinical testing of Neurgain's novel Parenchymal Delivery Injection ("PDI") system, which is designed to allow for the administration of cells to the spinal cord without stopping the patient's respiration. 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. Lineage also will be hosting an OPC1 Investor and Analyst Day on February 22, 2021 to provide details on recent OPC1 milestones and plans for 2021.

Lineage will evaluate the Neurgain PDI system's ability to safely and effectively deliver OPC1, Lineage's allogeneic oligodendrocyte progenitor cell (OPC) transplant, to the spinal cord in both preclinical and clinical studies beginning this year. If results from the PDI system are positive, then 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 PDI system into a later-stage clinical trial and if approved, commercial use of OPC1 for the treatment of patients with a cervical spinal cord injury. There currently are no U.S. Food and Drug Administration ("FDA") approved treatments for spinal cord injury.

Brian M. Culley, Lineage CEO stated, "Several months ago, we announced we had significantly improved the process for manufacturing OPC1, leading to large increases in purity and scale. More recently, we successfully developed a new 'thaw-and-inject' formulation, eliminating the commercially undesirable steps of handling and preparing cells one day prior to their use. Today, we are announcing another valuable improvement to the OPC1 program: access to a novel and convenient delivery system, which reduces a significant technical hurdle of conducting a larger-scale clinical trial. The Neurgain PDI offers an easier, potentially safer, and commercially more attractive option to treat SCI patients and is preferable to the complicated gantry utilized in an earlier study. It also will allow us to incorporate our new 'thaw-and-inject' formulation of OPC1, thereby enabling faster patient enrollment via access to a larger number of clinical trial sites. Most importantly, the PDI can eliminate the need for a patient's respirator to be turned off during the procedure, facilitating a measured and targeted transplantation of cells to the affected area."

"We look forward to collaborating with Lineage on their novel OPC1 program and demonstrating the value that Neurgain's PDI system can provide for the effective delivery of cell therapies in general and for the treatment of spinal cord injury in particular," stated Michael Krupp, Neurgain CEO.

Brian Culley added, "Similar to our alliance with Gyroscope Therapeutics for the Orbit Subretinal Delivery System, this new partnership with Neurgain delivers on our stated commitment to identifying and deploying optimal combinations of allogeneic cell therapies, modern manufacturing techniques, and superior delivery solutions in pursuit of our goal of becoming the pre-eminent allogeneic cell transplant company."

The Neurgain PDI System has been designed to provide specific, on-target delivery of cells with accurate dosing. The PDI system is more compact than existing devices and it is attached directly to the patient during the procedure. It is comprised of a platform and manipulator with a disposable magnetic needle assembly. This novel delivery system is expected to provide a significant improvement in usability and precision 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 acute cervical SCI.

About Spinal Cord Injuries

A spinal cord injury (SCI) 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. There are no FDA-approved drugs specifically for the treatment of SCI. 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 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. 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 and Orphan Drug designation from the FDA.

About the OPC1 Clinical Study

The "SCiStar" Study of OPC1 is an open-label, 25-patient, single-arm trial testing three sequential escalating doses of OPC1 administered 21 to 42 days post-injury in patients with subacute motor complete (AIS-A or AIS-B) cervical (C-4 to C-7) acute spinal cord injuries (SCI). Patient enrollment in this study is complete; 96% of patients reported one level of improved motor function and 33% of patients reported two levels of improved motor function. Patients continue to be evaluated on a long-term basis. Patients enrolled in the study had experienced severe paralysis of the upper and lower limbs. The primary endpoint in the study was safety. Secondary outcome measures included neurological function 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.

About Neurgain Technologies, Inc.

Neurgain Technologies (NGT) was founded in 2013 to develop technologies focused on the treatment of neurodegenerative diseases and neuropathic pain. Neurgain is developing a novel gene therapy technology and delivery devices to treat chronic neuropathic pain and spinal spasticity. 7-8% of the population suffers from Neuropathic Pain. Current therapeutic management is not working: Drugs in use have poor efficacy, and cause undesirable side effects such as resistance, addiction, and other disorders. NGT's mission is to positively impact this problem by means of our patented innovation to provide a therapy that works and improves the patient's quality of life. The Company is developing two assets: 1. Spinal subpial gene delivery platform (device), 2. Pre-clinical gene therapy for severe neuropathic pain. NGT plans to license the platform delivery technologies to multiple pharma/biotech which are developing gene or cell therapies in CNS. Neurgain's business strategy involves the out-licensing of spinal cord delivery technology and clinical development of a gene therapy for neuropathic pain and chronic spasticity. For more information, please visit https://neurgaintech.com/.

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 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 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 the potential benefits of using the Neurgain PDI device. 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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