Lineage Announces Dosing of First Patient in New Clinical Study of OPC1 for Subacute and Chronic Spinal Cord Injury

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- **Successful First-In-Human Use of New Parenchymal Spinal Delivery System**
- **First-ever Administration of OPC1 to a Chronic Injury Patient**

CARLSBAD, Calif.--(BUSINESS WIRE)--Aug. 4, 2025-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel allogeneic, or "off the shelf", cell therapies for serious neurological and ophthalmic conditions, announced today that the first-ever chronic spinal cord injury patient has been treated in the Company's DOSED (Delivery of Oligodendrocyte Progenitor Cells (OPCs) for Spinal Cord Injury: Evaluation of a Novel Device) clinical study at UC San Diego Health. The DOSED study is designed to evaluate the safety and utility of a new parenchymal spinal delivery system, a novel delivery device developed to deliver OPC1 directly to the site of injury in patients with spinal cord injury (SCI), and will enroll both subacute (between 21 to 42 days following injury) and chronic (between 1 to 5 years following injury) SCI patients. OPC1 is an investigational, allogeneic stem cell-derived cell transplant, comprised of oligodendrocyte progenitor cells. OPC1 is designed to replace or support cells in the injured spinal cord that are absent or dysfunctional due to traumatic injury and is intended to help restore or augment functional activity in persons suffering from an SCI. Improved functional activity can lead to greater mobility and enhanced quality of life for patients and significant cost-savings for caregivers. The first patient treated in DOSED was a neurologically complete SCI injury (American Spinal Injury Association Impairment Scale [AIS] grade A), with a single neurological level of injury (NLI) from T1 to T10, and the novel spinal delivery system successfully administered the intended one-time injection of 10 million OPC1 cells.

"Differentiated cell transplantation is a promising therapeutic approach that is increasingly being validated in a wide range of diseases and conditions. For this reason, it is exciting to advance the OPC1 program into further clinical testing and expand the OPC1-treated population to include chronic SCI patients," stated Brian M. Culley, Lineage's CEO. "DOSED is the third clinical study of OPC1 and is evaluating a superior delivery system, designed to deliver our proprietary cells over several minutes and without the need for stopping patient ventilation during administration. The delivery system is also compatible with a forthcoming immediate-use thaw-and-inject formulation of OPC1 that we developed for this program, which will eliminate the lengthy dose preparation steps conducted in prior studies. This is the first time OPC1 has been administered to a patient with a chronic spinal cord injury, which is an important milestone because those patients represent an additional and larger potential treatable population for this experimental therapy. In addition to evaluating the safety and performance of the new delivery device, we also will be collecting functional assessments on all patients, which gives us the opportunity to investigate any signals of efficacy that may arise in these patients. We are pleased the first-ever use of this custom delivery solution had a successful outcome with no administration issues and look forward to opening this study to additional sites."

OPC1 has extensive long-term safety data from two prior clinical trials: a five-patient Phase 1 safety trial in acute thoracic SCI, where all active subjects have been followed for at least 13 years; and a 25-patient Phase 1/2a multicenter dose-escalation trial in subacute cervical SCI, where all active subjects have been evaluated for at least 7 years. Long-term safety monitoring is ongoing for both studies, with no unexpected serious adverse events attributable to the OPC1 transplant being reported to date. Results from both studies have been published in the *Journal of Neurosurgery: Spine.* The Phase 1/2a publication of OPC1 in subacute cervical SCI is available here and the publication from the Phase 1 clinical study of OPC1 in acute thoracic SCI is available here. The OPC1 program was one of the first cell therapy clinical trials to be supported by the California Institute for Regenerative Medicine (CIRM) under Proposition 71. A publication focused on outlining the Magnetic Resonance Imaging (MRI) evidence from the 25-patient Phase 1/2a multicenter dose-escalation trial of OPC1 in subacute cervical SCI is also forthcoming.

Lineage founded the Annual Spinal Cord Injury Investor Symposium in 2023 and has co-sponsored the event in partnership with The Christopher & Dana Reeve Foundation in each year since then. The goals of this collaborative effort include increasing disease awareness, improving the probability of success in product development, and supporting clinical trial participation. The Reeve Foundation is dedicated to curing spinal cord injury by funding innovative research and improving the quality of life for individuals and families impacted by paralysis. Presenting companies have included AbbVie, Mitsubishi Tanabe, Neuralink, NervGen Pharma, Neuvotion, NovaGo Therapeutics, ONWARD, Paradromics and Synchron.

About OPC1

OPC1 is an oligodendrocyte progenitor cell (OPC) transplant therapy designed to provide clinically meaningful recovery in, and improvements to, motor function in individuals with spinal cord injuries (SCIs). OPCs are naturally occurring precursors to the cells that provide electrical insulation for nerve axons in the form of a myelin sheath. SCI most often 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. In the U.S., there are approximately 18,000 new spinal cord injuries annually and over 300,000 patients in total living with spinal cord injuries. There currently are no FDA-approved drugs or interventions specifically for the treatment of SCI. The clinical development of OPC1 has been partially funded by a $14.3 million grant from CIRM. OPC1 has received Regenerative Medicine Advanced Therapy (RMAT) designation and Orphan Drug designation from the U.S. Food and Drug Administration (FDA).

A selection of patient focused media related to the OPC1 program is available on the Media page of the Lineage website.

- Lineage's OPC1 program featured on CNN: "*He was paralyzed his last day of high school. How an experimental trial is showing 'unexpected improvement*"
- OPC1 patient spotlight – Chris Block's story
- OPC1 patient spotlight – Lucas Lindner's story

About the DOSED Study

The Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device (DOSED) clinical study is an open label, multi-center, device safety study, in 3-5 subacute and 3-5 stable chronic subjects with complete (ASIA Impairment Scale A) or incomplete (ASIA Impairment Scale B), traumatic, focal SCI affecting either cervical (C4-C7) or thoracic (T1-T10) vertebrae (ClinicalTrials.gov Identifier: NCT06841770). The primary objective of this study is to evaluate the safety of a novel Manual Inject Parenchymal Spinal Delivery System (MI PSD System) to administer OPC1 to the spinal parenchyma. The primary endpoint is frequency and severity of the MI PSD System- or injection procedure-related adverse events (AEs) through 30 days (1 month). Secondary endpoints are frequency and severity of AEs through 90 days (3 months) following injection of OPC1 and/or the concomitant immunosuppression administered, and incidence of MRI findings indicative of deterioration or safety-related changes at 90 days post-administration of OPC1. Exploratory endpoints include measurements of neurological impairment and function, as well as pain, evaluated by changes from baseline on the following endpoints: changes in neurological function as measured by sensory and motor scores and motor level on International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) examinations; changes in post-injection pain, defined as a worsening of pain or neuropathic pain of greater than 7 days duration from baseline levels, as assessed by the International Spinal Cord Injury Pain Basic Data Set or occurrence of allodynia; changes from baseline at 30, 90 and 365 days post-injection of OPC1 in: ISNCSCI, SCIM, International Spinal Cord Injury Pain Questionnaire; patient and clinical impressions of changes in quality of life as reported by changes from baseline at 30, 90, and 365 days post-injection of OPC1 as measured by: Patient Global Impression of Severity (PGI-S), Patient Global Impression of Change (PGI-C), Clinician Global Impression of Severity (CGI-S) and Clinician Global Impression of Change (CGI-C). Lineage also currently plans to seek approval from the FDA to introduce its new forthcoming immediate-use thaw-and-inject formulation of OPC1 into the DOSED study.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing allogeneic, or “off the shelf”, cell therapies for serious neurological and ophthalmic conditions. Lineage’s programs are based on its proprietary cell-based technology platform and associated development and manufacturing capabilities. From this platform, Lineage designs, develops, manufactures, and tests specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. These cells are created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages are transplanted into patients in an effort to replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and to restore or augment the patient’s functional activity. Lineage’s neuroscience focused pipeline currently includes: (i) OpRegen ® cell therapy, a retinal pigment epithelial cell therapy in Phase 2a development under a worldwide collaboration with Roche and Genentech, a member of the Roche Group, for the treatment of geographic atrophy secondary to age-related macular degeneration; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of spinal cord injuries; (iii) ReSonance (ANP1), an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; (iv) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage; and (v) RND1, a novel hypoimmune induced pluripotent stem cell line being developed under a gene editing partnership. For more information, please visit www.lineagecell.com or follow the company on X/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,” “aim,” “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. Forward-looking statements are based upon Lineage’s current expectations and beliefs and involve assumptions that may never materialize or may prove to be incorrect. Forward-looking statements in this press release include, but are not limited to, statements relating to: the plans and expectations with respect to OPC1 and its potential benefits, including its potential to improve replace or support cells in the spinal cord that are absent or dysfunctional due to traumatic injury and help restore or augment functional activity and lead to more mobility than what could otherwise be expected and enhanced quality of life for SCI patients, including chronic SCI patients, and significant cost-savings for caregivers; the potential benefits of MI PSD System in administering OPC1; the potential approval by FDA of the introduction of an immediate-use formulation of OPC1 into clinical testing and the potential benefits of such formulation; the planned expansion of the DOSED study to multiple study sites; and the potential market opportunity for OPC1, if approved, including its potential to be the first FDA-approved intervention specifically for the treatment of SCI. 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, but not limited to, the following risks: that Lineage is early in its development efforts and its investigational allogeneic cell therapies represent a novel and unproven approach to the treatment of serious and complex medical conditions; that positive findings in early clinical and/or nonclinical studies of a product candidate or delivery device may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate or device; the potential for delays in commencement, expansion, enrollment, data readouts, and completion of Lineage’s clinical studies, including due to delays in or the nature of FDA feedback or additional information requests; unexpected adverse side effects, inadequate efficacy, or other unfavorable results of Lineage’s product candidates in clinical studies that may limit their continued development, potential for regulatory approval, and/or commercial potential; Lineage’s dependence on third parties to conduct clinical studies of its product candidates and to manufacture and supply delivery systems or devices for administration of its product candidates, and the risk that such third parties or their products may not perform as expected; that Lineage may not obtain sufficient additional capital to complete the development and seek regulatory of or to commercialize its product candidates, if approved; that Lineage may not receive additional funding from CIRM to support the DOSED study which could adversely impact Lineage’s ability to expand and/or complete the study; that the ongoing Israeli regional conflict may materially and adversely impact Lineage’s manufacturing processes, including cell banking and product manufacturing for its product candidates, all of which are conducted by its subsidiary in Jerusalem, Israel; that Lineage may not be able to manufacture sufficient clinical quantities of its product candidates in accordance with current good manufacturing practice or at a cost-effective or commercially viable scale; that Lineage may not be able to maintain, or obtain the benefits associated with, the RMAT and orphan drug designations of OPC1 from the FDA; and those risks and uncertainties inherent in Lineage’s business and other risks discussed in Lineage’s filings with the Securities and Exchange Commission (SEC). 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 filed with the SEC and its other subsequent reports, which are available on the SEC’s website at www.sec.gov. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. Lineage undertakes no obligation to update any forward-looking statement 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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