Lineage Announces Notice of Allowance of Two Patents Covering Processes for Manufacturing Allogeneic Oligodendrocyte Progenitor and Retinal Pigmented Epithelium Cells

October 10, 2022

CARLSBAD, Calif.--(BUSINESS WIRE)--Oct. 10, 2022-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, announced today that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance to grant a patent for the Company's U.S. patent application No. 16/750,975, entitled "Dorsally-Derived Oligodendrocyte Progenitor Cells From Human Pluripotent Stem Cells," with claims covering proprietary manufacturing processes developed by Lineage for its oligodendrocyte progenitor cell therapy candidate (OPC1) for the treatment of spinal cord injury (SCI). The patent, which is expected to be issued in the coming months, would have a term that would expire no earlier than 2040. Additionally, the Company announced that the European Patent Office (EPO) has issued a notice of Intention to Grant a patent for Lineage's patent application entitled "Preparation of Retinal Pigment Epithelium Cells," (European Patent Application 16753990.7).

"These new patents highlight our ability to generate differentiated cell types from undifferentiated pluripotent cells and are valuable outputs from our platform. The production of specific cell lineages in a controlled and reproducible manner, on platforms which can support large-scale clinical trials, provide us with an important competitive advantage," stated Brian M. Culley, Lineage CEO. "In addition to extending the patent coverage of our assets, new IP can also permit us to protect our programs without relying on patents licensed or obtained from third parties, which may reduce or eliminate payments to such third parties and retain more value for Lineage."

Lineage aims to provide cell-based therapeutic benefits to patients by replacing cells lost due to disease, aging, or in the case of spinal cord injury, a traumatic event. The Company currently is focused on preparing for a planned interaction with the U.S. Food and Drug Administration (FDA) this quarter to discuss its OPC1 Investigational New Drug (IND) amendment submission, which would enable the clinical performance and safety testing of an improved delivery system to administer OPC1 in both acute and chronic spinal cord injury patients. In support of the Company's planned regulatory interactions, most of the verification and validation activities for this novel parenchymal spinal delivery system and its preclinical testing have been completed, with additional preclinical activities also near completion.

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 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 five allogeneic ("off-the-shelf") product candidates: (i) OpRegen, a retinal pigment epithelial cell therapy in development for the treatment of geographic atrophy secondary to age-related macular degeneration, is being developed under a worldwide collaboration with Roche and Genentech, a member of the Roche Group; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; (iii) VAC2, a 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; (iv) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; and (v) PNC1, a photoreceptor neural cell therapy for the treatment of vision loss due to photoreceptor dysfunction or damage. 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," "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. Such statements include, but are not limited to, statements relating to: the issuance of patents within the coming months and their terms for expiration; the potential value and benefits of these patents; any potential competitive advantages of our cell production capabilities; our ability to reduce or eliminate third-party payments through the development of new intellectual property; our collaboration and license agreement with Roche and Genentech and the timing of anticipated FDA interactions, preclinical activities, clinical trials, and clinical data updates related to our programs. 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 patents we expect to be issued may not be issued as soon as expected or at all, or if issued, may expire earlier than expected; that potential benefits of newly developed intellectual property to the Company may not be realized as quickly as expected or at all; that we may need to allocate our cash to

unexpected events and expenses causing us to use our cash more quickly than expected; that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; that competing alternative therapies may adversely impact the commercial potential of OpRegen; that Roche and Genentech may not successfully advance OpRegen or be successful in completing further clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction; that we may not establish new partnerships or expand existing collaborations; that Lineage may not be able to manufacture sufficient clinical quantities of its product candidates in accordance with current good manufacturing practice; 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). 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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