Lineage Announces Pipeline Expansion to Include Auditory Neuronal Cell Therapy for Treatment of Hearing Loss

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- **Expansion of Pipeline Into a Third Neuronal Cell Type Builds on Existing Capabilities**
- **Intellectual Property Has Been Filed Covering Composition and Methods for Generating Auditory Neuronal Progenitors**
- **Hearing Loss Afflicts More Than 5% of the Population; More Than 430 Million People**

CARLSBAD, Calif.--(BUSINESS WIRE)--Mar. 21, 2022-- 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 the Company is expanding its novel cell therapy pipeline to include a new investigational product candidate, an auditory neuronal cell transplant for the treatment of hearing loss, with an initial focus on the treatment of auditory neuropathy spectrum disorders. To support this new therapeutic effort, Lineage has filed for intellectual property covering the composition and methods for generating auditory neuronal progenitors which may be capable of functioning as sensory neurons and the connecting neuronal ganglion cells of the ear, and to methods of treatment that employ these cells for the potential treatment of auditory neuropathy. According to the World Health Organization, hearing loss currently afflicts over 5% of the world's population, or more than 430 million people, and by 2050 it is estimated that one in every ten people, or more than 700 million people, will have disabling hearing loss.

"Hearing loss is a major sensory deficit which affects an enormous number of individuals worldwide, yet current approaches leave much room for improvement. I am pleased to be advising Lineage and providing insights and experience in the launch of this new endeavor and working toward developing cell-based solutions for this condition," stated Stefan Heller, Ph.D., Edward C. and Amy H. Sewall Professor, Stanford University School of Medicine, Department of Otolaryngology – Head & Neck Surgery and Institute for Stem Cell Biology and Regenerative Medicine ISCBRM.

"We are excited to announce this new, internally-developed initiative for Lineage, and to do it so quickly following the partnership we announced with Roche and Genentech for our lead program, OpRegen®, in a deal worth up to $670M USD," added Brian Culley, Lineage CEO. "Many patients with sensorineural hearing loss are poorly addressed, cannot benefit from cochlear implants, and/or have no FDA-approved treatment options. Similar to OpRegen, which has demonstrated to be able to replace and restore retinal pigment epithelium cells in patients with vision loss, and OPC1, which similarly replaces oligodendrocytes for the treatment of spinal cord injury, replacing auditory neurons or augmenting an existing but damaged auditory neuron population may provide a benefit beyond the reach of alternate approaches such as prostheses. We believe auditory neuronal transplants represent a unique opportunity to leverage our knowhow and capabilities in cellular differentiation into a fourth indication with a large unmet need. In addition to the speed with which the team created this new program from our internal technology, we have done so with a modest investment of capital so far, because we were able to take advantage of our established manufacturing infrastructure and broad knowhow in the expansion and differentiation of pluripotent cells. This is another example of the efficiency and versatility of our technology platform, which is gaining broader awareness, and which offers us a favorable competitive position in the emerging fields of regenerative medicine and anti-aging technologies."

Auditory neuropathy is a hearing disorder in which the inner ear successfully detects sound but has a problem with sending signals from the ear to the brain. Current state of the art medical knowledge suggests that auditory neuropathies play a substantial role in hearing impairments and deafness. Hearing depends on a series of complex steps that change sound waves in the air into electrical signals. The auditory nerve then carries these signals to the brain. Outer hair cells help amplify sound vibrations entering the inner ear from the middle ear. When hearing is working normally, the inner hair cells convert these vibrations into electrical signals that travel as nerve impulses to the brain, where the brain interprets the impulses as sound. Auditory neuropathy can be caused by a number of factors including: (i) damage to the auditory neurons that transmit sound information from the inner hair cells – specialized sensory cells in the inner ear – to the brain; (ii) damage to the inner hair cells themselves; (iii) inherited genes with mutations or suffering damage to the auditory system, either of which may result in faulty connections between the inner hair cells and the auditory nerve, which leads from the inner ear to the brain; or (iv) damage to the auditory nerve itself. Researchers are still seeking effective treatments for those affected with auditory neuropathy.

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 four 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, which is now 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 and (iv) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy. 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 collaboration and license agreement with Roche and Genentech and activities expected to occur thereunder, the upfront, milestone and royalty consideration payable to Lineage and Lineage’s planned use of proceeds therefrom; the potential benefits of treatment with OpRegen, the potential success of other existing partnerships and collaborations, the broad potential for Lineage’s regenerative medicine platform and Lineage’s ability to expand the same; Lineage’s plans to advance its spinal cord injury, oncology and auditory neuron programs and announce new disease settings where it plans to deploy its technology; the projected timing of milestones of future studies, including their initiation and completion, the projected timing of interactions with the FDA to discuss product designation, manufacturing plans and improvements, and later-stage clinical development; the potential opportunities for the establishment or expansion of strategic partnerships and collaborations and the timing thereof, and the potential for Lineage’s investigational allogeneic cell therapies to generate clinical outcomes beyond the reach of traditional methods and provide safe and effective treatment for multiple, diverse serious or life threatening conditions. 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 risk that competing alternative therapies may adversely impact the commercial potential of OpRegen, which could materially adversely affect the milestone and royalty payments payable to Lineage under the collaboration and license agreement, the risk that Roche and Genentech may not be successful in completing further clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction, the risk that Lineage might not succeed in developing products and technologies that are useful in medicine and demonstrate the requisite safety and efficacy to achieve regulatory approval in accordance with its projected timing, or at all; the risk that Lineage may not be able to manufacture sufficient clinical and, if approved, commercial quantities of its product candidates in accordance with current good manufacturing practice; the risks related to Lineage’s dependence on other third parties, and Lineage’s ability to establish and maintain its collaborations with these third parties; the risk that government-imposed bans or restrictions and religious, moral, and ethical concerns about the use of hES cells could prevent Lineage or its partners from developing and successfully marketing its stem cell product candidates; the risk that Lineage’s intellectual property may be insufficient to protect its products; the risk that the COVID-19 pandemic or geopolitical events may directly or indirectly cause significant delays in and substantially increase the cost of development of Lineage’s product candidates, as well as heighten other risks and uncertainties related to Lineage’s business and operations; 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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