Lineage Cell Therapeutics Issues Letter to Stockholders

January 6, 2025

CARLSBAD, Calif.--(BUSINESS WIRE)--Jan. 6, 2025-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today published a letter to shareholders highlighting the company's recent achievements and outlook for 2025.

Dear Fellow Shareholders,

We hope you had a restful holiday season and wish you a happy new year. As we look at our plans for the new year, we want to update you on our recent progress and explain why we believe 2025 will be an exciting year for our company.

As many of you know, Lineage is an emerging cell therapy company, but we more accurately should be referred to as a cell *transplant* company. The term cell transplant is more accurate because we do not administer "stem" cells to patients. Instead, we deliver mature, differentiated cells, which are guided along a specific lineage to become functionally identical to the cells which an individual has lost due to disease or trauma. Those cells are then transplanted in a one-time procedure to treat conditions caused by the loss or dysfunction of a specific cell type. We summarize this approach as "replace and restore". In the setting of dry-age related macular generation (dry-AMD), our manufacturing team creates new retinal pigment epithelial (RPE) cells to replace the RPE cells that have been lost by an individual after decades of use. This allogeneic cell therapy program, OpRegen®, led to a global development and commercialization partnership with Roche and Genentech, a member of the Roche Group. Our partners are currently evaluating OpRegen in a Phase 2a clinical trial. We also have established a pipeline of earlier-stage product candidates, each utilizing a single, carefully selected and cultured cell line for the life of a product, which eliminates donor variability and reduces regulatory risk. We believe we are the only publicly traded, non-oncology cell transplant company, which is one reason why we believe Lineage is the leading entity in this rapidly growing field of medicine.

Often, the most important things we do occur behind the scenes. Actions which increase our programs' probabilities of success do not always become press releases. And discoveries that we make may be more valuable to our shareholders as trade secrets than as patents. Last year was a great example of these circumstances; we made significant progress in many areas, advancing our programs, expanding collaborations, and strengthening our balance sheet to help reach important milestones in 2025 and beyond. However, these advances were masked by significant uncertainty in the biotech sector, which has continued for years, making value-creation in biotech increasingly difficult and, unsurprisingly, frustrating many investors.

This communication is intended to provide clarity and transparency into certain areas of our business and is an opportunity to provide relevant context and expectations for our audience which aren't normally covered in a press release. Those areas are: financing strategy, manufacturing capabilities, and our plans for long-term success. I aim to address each of those topics for both existing and future potential shareholders.

Financing – A Strong Foundation

For the past 6 years, Lineage has been funded by diverse sources of capital, including business development deals, sales of non-core assets, and an ATM facility. At their respective times, we believe each of these offered a better cost of capital than traditional investment bank-led financings. But traditional financings sometimes have advantages, and in particular, the "milestone-warrant" structure employed in our November financing was an ideal fit for our unique situation. However, the structure of that deal is complex and invites some clarity.

As many shareholders know, the company's future is tightly linked to whether our partners, Roche and Genentech, elect to advance OpRegen into its next phase of clinical development. A forthcoming "go/no-go" decision to conduct a controlled clinical trial of OpRegen will be a major event for Lineage and for OpRegen's probability of commercialization, so we sought not only to secure immediate capital, but also created a path to future capital, contingent in part upon the successful advancement of OpRegen by our partners into a controlled clinical trial.

In November, we closed on an initial $24 million in gross proceeds, and we expect to close on an additional $6 million later this month, subject to stockholder approval. Based on our current operational plan, we expect this capital will provide Lineage with runway into Q1 2027. In addition, we issued warrants for up to an additional $36 million at a strike price of at least $0.91, which included an acceleration (i.e. "call") of the warrants if and when the advancement of OpRegen into a controlled trial is disclosed. In a single transaction, we raised more than a year of capital and provided a path to a second year of capital if OpRegen meets the milestone defined in the warrant. We believe establishing this line-of-sight to additional capital reduces a future financial overhang and puts Lineage in greater control of its future with respect to capital raises or strategic discussions we may conduct with new or existing partners.

In the short-term, we expected the dilutive impact of this raise, because it was conducted in highly unfavorable market conditions, but it is important to run the business from a position of optionality and strength. Notably, based on our historic spending rates, we have capitalized the company potentially into mid-2028, subject to receiving the $36 million of warrant capital. And if certain alliance milestones, grants, and/or business development transactions that we are currently evaluating successfully close, Lineage could even be funded for the next *four* years. With this recent financing, we believe we have set Lineage on its strongest financial foundation in its history.

Manufacturing – Achieving the Unprecedented

One of the challenges of working in cell therapy is that many people restrict their scope of cell therapy to cancer, but the CAR-T field is unsustainably crowded with many poorly differentiated assets. We believe the more compelling growth opportunity in cell therapy resides in diseases and conditions *outside* of cancer, or what we like to call "noncology". There are only a few companies that have reached clinical testing with a "noncology" asset, including Bluerock (acquired by Bayer) for Parkinson's Disease, and Semma (acquired by Vertex) for Type 1 Diabetes. In fact, to our knowledge, Lineage is currently the *only* publicly traded company in which one can invest exclusively and directly in this exciting and increasingly validated branch

of medicine.

A second challenge is that a focus on clinical outcomes often overlooks the difficulty, or in some cases the feasibility, of manufacturing a product using a commercially-viable and scalable process. Autologous products are expensive because each dose is made for just one person, which precludes affordability in all but the most serious conditions (i.e. cancer). Allogeneic therapies, for which the cells are sourced from one donor but delivered to many patients, offer a *theoretical* solution to the problem of scale, but in our view, a truly affordable allogeneic process has not yet been reduced to practice by any company. Our view is that making 10, 100, or even 1,000 doses from a single donor fails to deliver on the intent or power of an allogeneic therapy. In fact, we call those approaches “shallow-geneic” because they lack the depth of a scalable process. They may be allogeneic by definition, but they are not sufficiently more scalable than autologous cell therapies, and therefore, do not genuinely address the issue of cost.

We believe the full vision of an off-the-shelf allogeneic therapy comes from scaling production by ten million, or even a hundred million-fold. To our knowledge, no company has yet demonstrated they can manufacture thousands of doses of their product from a stable Working Cell Bank (WCB), which itself was generated from a stable Master Cell Bank (MCB), and yet the multiplication stemming from that sequence of expansions is necessary to reach the commercially-desirable cost of goods implied from a “true” allogeneic product. Lineage aspires this year to be the first company to demonstrate this multiplicative scalable capability, using actual production lots. If we are successful, we believe it will help establish our manufacturing team as proven and capable leaders in cell therapy manufacturing.

Strategy and Future Goals – Planning for Success

The third message is how our development and financing decisions are linked to a longer-term vision of success for Lineage. We understand there are significant expectations on the ongoing OpRegen trial. While we believe our phase 1/2a results are compelling, validation and affirmation of our findings in a larger trial conducted by an international pharmaceutical company can reasonably be expected to add substantial credibility to our initial findings and future expectations. If OpRegen continues to perform as it has to date, we believe it will reflect positively on our team’s capabilities, our technology platform, and the value of the company.

Lineage is primarily known for OpRegen, but we are capable of much more than making RPE cells. A clearly articulated product portfolio, especially one that is generated from an internally-owned platform, can offer a compelling foundation for value creation. For this reason, we are establishing a pipeline of closely-related neurological cell transplant product candidates, which each employ our core technology, including: OPC1 (oligodendrocyte progenitors), to improve mobility following a severe spinal cord injury, ReSonance™ (auditory neuronal progenitors) to improve hearing in people suffering from sensorineural hearing loss, and a third, as yet undisclosed program. If OpRegen advances into a later-stage trial and our manufacturing objectives are reached, we believe our cost of capital will improve and allow us to move faster and farther with these programs. Once the power of our platform is further demonstrated and validated, we believe that the pipeline of internally-owned assets that we are advancing will make us a desirable partner for pharma and an attractive opportunity for investors.

Looking ahead, we will continue to support our partners in the development of OpRegen. In parallel, our internal focus will be on conducting the DOSED clinical study of OPC1, advancing ReSonance for the treatment of hearing loss, and other carefully chosen initiatives.

We remain committed to acting in the best interests of our shareholders and will continue to implement a thoughtful and staged approach to product development. We believe that long-term value and appreciation can be created through the advancement of our clinical and preclinical pipelines, where we intend to apply our technology and expertise to validate our unique cell transplant approach.

We appreciate your support and belief in our vision. We invite you to stay engaged with our progress through regular updates, earnings calls, and announcements.

Replace and Restore,

Brian Culley, CEO
Lineage Cell Therapeutics, Inc.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel, “off-the-shelf,” cell therapies to address unmet medical needs. 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, 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 in collaboration with Factor Bioscience Limited. 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. Lineage’s forward-looking statements are based upon its current expectations and beliefs and involve assumptions that may never materialize or may prove to be incorrect. Such statements include, but are not limited to, statements relating to: the potential therapeutic benefits of OpRegen in patients with GA secondary to AMD, as well as the clinical advancement of OpRegen and its impacts on us; our ability to successfully manufacture OpRegen at scale; statements relating to the terms of the financing described herein, which do

not purport to be complete and are qualified in their entirety by the full text of the financing documents, copies of which are attached as exhibits to our Current Report filed on Form 8-K on November 20, 2024, our ability to obtain stockholder approval to close on an additional $6 million in gross proceeds later this month and issue corresponding warrants, the acceleration of the expiration of the warrants in connection with the achievement of the OpRegen clinical milestone, or the exercise of the common warrants in cash prior to their expiration; that our cash, cash equivalents and marketable securities is sufficient to support our planned operations into 2027, or into 2028 assuming exercise of the warrants, or beyond 2028 assuming additional alliance milestones, grants, and/or business development transactions occur; the growth of cell therapy in diseases and conditions *outside* of cancer, relative to oncology cell therapy, or at all; the broad potential for Lineage's regenerative medicine platform and our ability to develop additional product candidates, including the commencement of the DOSED clinical study for OPC1; and the potential of our pipeline, platform technology and/or manufacturing capabilities, independently and/or in connection with the clinical advancement of the OpRegen program, to validate our approach or create value. 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 we may need to allocate our cash to unexpected events and expenses causing us to use our cash, cash equivalents and marketable securities more quickly than expected; that we are unable to obtain shareholder approval to close on an additional $6 million in gross proceeds and issue corresponding warrants; that the warrants may not be exercised for cash, including if the price per share of our common stock never reaches or exceeds the warrant exercise price of $0.91 per share, or that we do not have an effective registration statement on file at the time of exercise, or if other conditions contained in the warrants are not met; that development activities, preclinical activities, and clinical trials of our product candidates may not commence, progress or be completed as expected due to many factors within and outside of our control; 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 OpRegen may not clinically advance, and even if it does, that such advancement will not have a positive effect on us, our share price, our cost of capital, nor the overall success of the OpRegen program; that OpRegen may never be proven to provide durable anatomical functional improvements in dry-AMD patients; that competing alternative therapies may adversely impact the commercial potential of OpRegen; that Roche and Genentech may not be successful in obtaining regulatory approval for OpRegen in any particular jurisdiction; that the ongoing Israel-Hamas war and broader regional conflict may materially and adversely impact our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, all of which are conducted by our 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; 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 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. All forward-looking statements are expressly qualified in their entirety by these cautionary statements.

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