



Lineage Cell Therapeutics Provides Shareholder Update

December 19, 2019

CARLSBAD, Calif.--(BUSINESS WIRE)--Dec. 19, 2019-- [Lineage Cell Therapeutics, Inc.](#) (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cellular therapies for unmet medical needs, today provided a year-end review and an outline of clinical and business plans for 2020.

To Our Shareholders,

As we conclude 2019, we want to provide clarity on what our shareholders can expect from Lineage next year. Our objective for 2019 was to establish a foundation from which we could become a leading cell therapy company. Our greater goal is to usher in a new branch of medicine, based on transplanting intact cells into the body to restore activity lost to aging, injury, or disease, which we believe is the best path to long-term success. This year-long campaign required us to make major changes in three areas. One, we expanded our product portfolio by combining three complementary clinical-stage assets under one roof. Two, we sold or stopped non-core activities, which significantly reduced our expenses and headcount and focused our priorities. And three, we changed our leadership team, location, and company name. These steps have created an efficient and dynamic organization, which has goals that are clear and easy to communicate to the investment community, and which is on-track for success in 2020. A partial list of the major steps we undertook includes:

- Acquired Asterias Biotherapeutics, Inc., adding two clinical-stage cell therapy assets to our pipeline, providing diversification and allowing us to leverage manufacturing know-how developed by our dry age-related macular degeneration (dry AMD) OpRegen[®] program;
- [Signed](#) an exclusive Research and Option Agreement with Orbit Biomedical Ltd., providing us with a significant competitive advantage in the delivery of cells for dry AMD;
- Hired new management team members, including the CFO, General Counsel, and a newly-created position, VP of Business Development;
- Changed our name and relocated the corporate headquarters from the San Francisco Bay Area to Carlsbad, CA;
- Aggressively reduced our spending on non-core activities and lowered headcount from approximately 105 (pro forma immediately prior to Asterias closing) to approximately 50 at year-end, greatly reducing our 2020 operational budget from ~\$25M to ~\$16M.

During 2019, we were able to fund our operations primarily by selling some of our investments in OncoCyte and AgeX, two companies which originated at Lineage before becoming independent public companies. Because of their success, we have not had to do a traditional financing transaction with our own stock for more than two years, which distinguishes us among our peers and reflects well upon our ability to generate value from our extensive portfolio of patents and technologies.

In parallel with these structural changes, we also made substantial advancements with our clinical programs. We believe our 2019 clinical progress will help Lineage become more widely known in the investment and medical communities as our patient data matures and we continue to deliver on our stated milestones. Developing treatments in a new field necessarily requires a lot of time, but we are excited that after many years of effort, we are seeing signs of efficacy from our cell therapy programs. Important events and data updates from last year include:

- [Reported](#) positive clinical results from our Phase I/IIa clinical study of OpRegen in patients with dry AMD with geographic atrophy. Treatment with OpRegen continued to be well tolerated with better-vision patients able to read more letters on the ETDRS eye chart than before treatment (range of 10 to 19 additional letters correctly identified).
- Successfully dosed a patient for the first time using both the Orbit Subretinal Delivery System (Orbit SDS) and our new Thaw-and-Inject (TAI) formulation of OpRegen. The patient has experienced an improvement in vision and the migration to Orbit plus TAI provides substantial commercial advantages compared to alternative inferior approaches.
- Received a CE Mark for Renevia[®], with an intended use in adults for the treatment of facial lipoatrophy. The CE Mark enables us to sell Renevia in Europe and we are actively pursuing a commercialization partner for this activity.
- [Reported](#) a positive clinical update from our ongoing Phase I/IIa clinical trial of OPC1 for the treatment of acute spinal cord injury. The overall safety profile of OPC1 has remained excellent with robust motor recovery in the arms/hands maintained through year 2 follow-ups to date. Gains in motor function for patients assessed to date have continued, representing tremendously meaningful improvements to quality of life and independence.
- Awarded multi-million dollars in grants from the Israel Innovation Authority and the NIH and published or presented multiple papers and abstracts describing our work.
- Obtained patents associated with the manufacture of our unique cell types, adding additional protections to all three of our clinical programs, as well as patent rights describing the use of iPS cells, an alternate option for generating differentiated cells for transplant and treatment of diseases, further broadening the potential application of our work.

To learn more about our clinical programs, we invite you to listen to our KOL Day where renowned experts in ophthalmology and spinal cord injury discuss these conditions and Lineage's efforts to develop therapies for them. A full webcast is available here: <https://investor.lineagecell.com/events>

As we begin 2020, our focus will be to efficiently use our resources to support rapid clinical development of our programs, which we believe will help maximize near- and long-term shareholder value. We also will deploy a number of initiatives to increase awareness of our work and our recent accomplishments. Near term milestones our investors can look forward to include:

- **Complete patient enrollment** in the United States with the Orbit SDS in the ongoing Phase I/IIa clinical study of OpRegen for the treatment of dry AMD, expected in Q1 2020.
- **Obtain VAC2 immunogenicity data** from the initial patients in the ongoing Phase I study in NSCLC (non-small cell lung cancer) run by Cancer Research UK, expected around year end.
- **Present new OpRegen data** from the ongoing Phase I/IIa clinical study at the Association for Research in Vision and Ophthalmology Meeting (ARVO) in May 2020.
- **Advance the OPC1 manufacturing program** by introducing enhancements to the manufacturing process in our GMP manufacturing facility, ongoing throughout 2020.
- **Meet with the FDA** to discuss the manufacturing and clinical development of OPC1, around the middle of 2020.
- **Identify an external partner** for commercialization of Renevia in Europe, targeted for the first half of 2020.
- **Continue engagement** with the investment and medical communities with participation at medical and healthcare industry conferences, ongoing throughout 2020.
- **Strengthen existing partnerships** with the [National Institutes of Health](#), the [Israel Innovation Authority](#), the [California Institute for Regenerative Medicine](#) and [Cancer Research UK](#).

Additionally, we expect 2020 to feature significantly more business development activity. We only recently created the full-time position of Vice President of Business Development, yet we already have completed some small transactions which will be announced early next year. We also are pursuing opportunities to obtain development support for OpRegen, OPC1, and Renevia, through external partnerships, as well as evaluating our option to regain majority ownership and operational control of the VAC platform for oncology, if the data we obtain in 2020 support such a transaction.

Overall, our shareholders will have a lot to look forward to next year. With key structural changes now behind us, we are fully committed to combining operational excellence with an efficient capital plan to move forward our exciting programs in dry AMD, spinal cord injury and oncology. Revolutionary change does not happen quickly, and we appreciate your patience and continued support as we position Lineage as a leader in cell therapy and cell transplant medicine. We appreciate our shareholders' support and we look forward to sharing with you the next steps of this exciting journey.

Sincerely,
Brian M. Culley, CEO

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 proprietary cell-based therapy platform and associated 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 either to 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 assets include (i) OpRegen[®], a retinal pigment epithelium transplant therapy in Phase I/IIa 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 I/IIa development for the treatment of acute spinal cord injuries; and (iii) VAC2, an allogeneic cancer immunotherapy of antigen-presenting dendritic cells currently in Phase I development for the treatment of non-small cell lung cancer. Lineage is also evaluating potential partnership opportunities for Renevia[®], a facial aesthetics product that was recently granted a Conformité Européenne (CE) Mark. 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 Lineage's cost-savings efforts, manufacturing plans, enrollment activities, data presentations, clinical study advancement, drug evaluation, and anticipated operational budget for the year ending December 31, 2020. 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 14, 2019 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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