Lineage Cell Therapeutics Provides End of Year Shareholder Letter

December 28, 2020

CARLSBAD, Calif.--(BUSINESS WIRE)--Dec. 28, 2020-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today provided a year-end review and an outline of its plans for 2021.

To Our Shareholders,

As we reach the end of an eventful 2020, we are inspired by the many healthcare providers and biopharmaceutical companies that worked to combat the COVID-19 pandemic. This year has been difficult, but it has reinforced the importance of our mission: to treat and potentially even reverse the effects of serious diseases and conditions by advancing our novel cell therapy product candidates through clinical trials and into the hands of physicians. Although our industry has enjoyed many successes lately, those affected by the conditions we are focused on still need better choices.

Following changes to our leadership team in late 2018 and early 2019, we have sought to transform Lineage into the preeminent allogeneic cell transplant company. Our work began modestly, but we hit our stride in 2020 and reached important clinical, manufacturing, and business milestones this year, which created substantial value and advanced us toward our ultimate goal. In parallel, a number of cell therapy milestones were reached by other companies and academic institutions, strengthening our belief that the field has entered a turning point and is poised for explosive growth in the months and years ahead. We want to be prepared for that growth, so we are looking toward 2021 and mapping out additional milestones we want to deliver to our shareholders next year.

We are fortunate to have attracted may new shareholders this past year, so it is important from time to time to outline our basic approach to building a successful company and explain how it differs in advantageous ways from many others working in cell therapy.

Our basic approach is akin to transplant medicine, in which specific cell types are used to replace the ones which have been lost to disease, not unlike a bone marrow transplant. In certain settings, we believe that transplanting whole human cells can offer a more attractive safety profile and predictable behavior than introducing foreign molecules into the body.

Most importantly, our therapeutic products are derived from well-characterized pluripotent stem cell lines. These cells can become any of the cell types in your body, from bone to brain to blood, and starting with pluripotent stem cell lines means we have a virtually unlimited supply of starting material. From these cells we apply proprietary methods to manufacture pure populations of only the cell types which we wish to use in patients. Notably, we never modify the DNA of these cells, which avoids some of the safety concerns that have been reported with certain gene-editing technologies.

Deriving cell therapy products from pluripotent stem cells offers a second critical advantage; it allows our cells to be used as allogeneic or “off the shelf” transplants in patients – an approach which offers major advantages in terms of cost and scale of production, and which may be able to offer additional benefits which traditional therapeutic modalities are unable to achieve, such as restoring lost tissue.

We next make intelligent investments in our manufacturing and delivery methods, to help establish best-in-class products for end-users and strong competitive advantages to protect our products and intellectual property over the long term. As a reminder, there currently is no FDA approval pathway to develop a generic or biosimilar copy of a cell therapy product, which provides a significant barrier-to-entry from generic competition.

Finally, we seek to generate compelling clinical data to support moving into late-stage clinical trials and eventual marketing authorizations. We believe that we already are seeing data that supports advancing all three of our clinical-stage products into additional trials which, in some cases, may be registrational.

Therapeutic product development is a long process, but we’re making great progress. Our goal of building Lineage into the preeminent cell therapy company is ambitious but attainable. We know of no other company that possesses a comparable combination of cell therapy patent breadth, in-house manufacturing capabilities, and encouraging clinical evidence in three distinct disease areas, each with large unmet medical needs and billion-dollar commercial opportunities. The safety and efficacy data we have seen to date encourages us to continue advancing our product candidates closer to late-stage clinical trials and potential corporate partnerships.

In addition to our overall product development strategy, we’ve conducted some transactions which can help build value for Lineage shareholders over the longer term. For example, we have successfully monetized portions of Lineage’s non-core patent portfolio, including through the creation and subsequent sale of businesses like AgeX and OncoCyte, transactions which helped fund our clinical programs without the need for traditional equity financings. It is worth highlighting that we have not needed to conduct a traditional equity financing in more than three years, avoiding the dilution that comes along with such offerings during a period of significant business transition. We also have established a culture of responsible spending and cost cutting to advance our programs in the most efficient way possible. Furthermore, we have enjoyed significant cost synergies by combining all of our manufacturing activity at one facility, sequentially applying our team’s know-how and best practices to all three clinical programs without having to increase our headcount.

The most significant milestones we achieved in 2020 include:

- Completion of enrollment in a 24 patient Phase 1/2a clinical study of OpRegen® for the treatment of dry age-related macular degeneration (AMD) with geographic atrophy (GA) with encouraging preliminary signs of tolerability and efficacy;
- Announcing the first known finding of retinal tissue restoration in a patient who received a retinal pigment epithelium (RPE) cell transplant;

- Making major manufacturing improvements to our OPC1 acute spinal cord injury (SCI) program, including to the process, purity, potency, and scale, and to the development of a "ready-to-inject" formulation, enabling use at a much larger number of treatment centers;
- The early exercise of our option with Cancer Research UK to bring the VAC immuno-oncology platform in-house; and
- Reporting encouraging preliminary Phase 1 clinical study results with VAC2 for the treatment of non-small cell lung cancer with high levels of antigen-specific immunogenicity observed.

The achievement of these milestones, alongside increased efforts to generate awareness about Lineage's mission, have led to meaningful share appreciation this past year. Looking ahead, we believe the field of cell therapy will experience years of rapid growth, especially in conditions for which small molecules or antibodies have failed, such as dry AMD and spinal cord injuries. In oncology, we believe that innate immune cells such as our dendritic cells will enjoy a resurgence as a promising complement to chimeric antigen receptor T cells (CAR-T) and more recently, the emerging natural killer (NK) cell therapies. We seek not only to be well-positioned for that growth, but also to contribute to the understanding that allogeneic approaches are generating a growing body of safety and efficacy data which can lead to compelling commercial advantages and clinical outcomes.

Among our 2021 objectives will be to move all three of our clinical programs forward, achieve further improvements in our overall product profiles via manufacturing and delivery system improvements, and enter into validating and enabling partnerships to accelerate our timelines. An additional objective this year will be to build greater awareness for our past achievements and our future plans.

Some of the events and milestones that our shareholders can look forward to in 2021 include:

- Present new and accumulated OpRegen data from the ongoing Phase 1/2a clinical study on two occasions during the first and second quarters of 2021;
- Complete VAC2 patient enrollment in the ongoing Phase 1 clinical study for the treatment of non-small cell lung cancer by the end of the first quarter of 2021;
- Evaluate delivery device solutions for our OPC1 program, enabling access to a greater number of clinical sites, currently ongoing and throughout 2021;
- Meet with the FDA to discuss further development of the OPC1 program, including a late stage clinical study, during the first half of 2021;
- Host a Therapeutic Expert Call to discuss our OPC1 program for the treatment of spinal cord injury, in January or February of 2021;
- Evaluate opportunities for new VAC product candidates based on newly discovered tumor antigens/neoantigens, throughout 2021;
- Evaluate partnership opportunities and expansion of existing external collaborations and identification of new collaborations for OpRegen, OPC1 and VAC2, currently ongoing and throughout 2021; and
- Continuing to participate in a large number of investor and partnering meetings and medical and industry conferences to broaden the knowledge of our work.

This is an exciting time to be part of the greater Lineage family because our technologies give us an opportunity to make a profound impact on an enormous number of people. As we have seen this year, there is no other industry which can impact the human condition as much as biopharmaceuticals can, and patient need provides us with inspiration each and every day. To understand better what that means on a personal level, we encourage you to visit our Media page and hear directly from the patients whom we aim to treat and their families. We are thankful for the courage and trust of patients who participate in our clinical studies and we are grateful to our shareholders for sharing our work with their friends and their continued support of our efforts.

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 three 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, a leading cause of blindness in the developed world; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; and (iii) VAC, an allogeneic dendritic cell therapy platform for immuno-oncology and infectious disease, currently in clinical development for the treatment of non-small cell lung cancer. 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 the potential growth of the cell therapy field and Lineage's planned investor presentations, manufacturing improvements, regulatory meetings, and partnership discussions. 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 12, 2020 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20201228005066/en/

Lineage Cell Therapeutics, Inc. IR
Ioana C. Hone
(ir@lineagecell.com)
(442) 287-8963

Solebury Trout IR
Gitanjali Jain Ogawa
(Gogawa@troutgroup.com)
(646) 378-2949

Russo Partners – Media Relations
Nic Johnson or David Schull
Nic.johnson@russopartnersllc.com
David.schull@russopartnersllc.com
(212) 845-4242

Source: Lineage Cell Therapeutics, Inc.