



Lineage Cell Therapeutics to Apply Allogeneic Dendritic Cell Therapy Program to COVID-19 Vaccine Development

May 5, 2020

Grant Application Submitted to California Institute for Regenerative Medicine for Additional Funding

CARLSBAD, Calif.--(BUSINESS WIRE)--May 5, 2020-- [Lineage Cell Therapeutics, Inc.](#) (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs, announced today that it has applied for grant funding from the [California Institute for Regenerative Medicine](#) (CIRM) to support the use of VAC, Lineage's allogeneic dendritic cell therapy, toward the development of a potential vaccine against SARS-CoV-2, the virus which causes COVID-19. In response to the COVID-19 pandemic, CIRM recently approved emergency funding and the allocation of \$5 million for peer-reviewed regenerative medicine and stem cell research that could quickly advance treatments for COVID-19. The funding would be awarded as part of an expedited approval process.

"Several lines of clinical evidence encouraged us to apply the use of the VAC technology to the development of a prophylactic vaccine against SARS-CoV-2 and other coronaviruses," stated Brian M. Culley, Lineage CEO. "Recent publications have reported that patients infected with coronaviruses can exhibit modest neutralizing antibody titers and diminished T cell responses, suggesting it may be difficult for traditional vaccine approaches to generate long-term protection via the cellular immune response. Our belief is that dendritic cells, the body's most potent antigen-presenting cell, can present viral antigens to the immune system to prime a robust immunological memory and provide durable, multi-year protection against the severe consequences of infection. This would be especially beneficial for front-line healthcare workers and others at risk of repeated exposure. Clinical data in patients with various cancers collected by Duke University Medical Center in early clinical trials of VAC1, the first product candidate from the VAC platform, showed nearly all patients developed evidence of antigen-specific T cell immune responses. This signal was confirmed in a majority of patients enrolled in a subsequent phase 2 study of VAC1 reported in 2016 by Asterias Biotherapeutics, which Lineage acquired in 2019. We believe these and additional data provide validation of the underlying mechanism of using dendritic cells to present antigens to the body's immune system. We believe we are unique among cell therapy companies that are evaluating solutions to the COVID-19 pandemic because we are not focused on late-stage critical care, but on providing long-term prophylactic protection against infection, which may help reduce the need for hospitalization and address a critical gap among the critical care and humoral immunity approaches currently in development. The ideal scenario is that protection against COVID-19 in high-risk individuals would become durable, similar to measles or pertussis, rather than influenza, which requires an annual vaccination."

Mr. Culley continued, "Presenting a viral antigen by means of our allogeneic dendritic cell platform will require manufacturing process development and creating a new expression construct prior to submitting an Investigational New Drug (IND) application to enable clinical evaluation. This will entail a modest investment of capital, but we feel that we are able to manage this new program alongside our existing programs in dry AMD and spinal cord injury. We recently raised \$3.8M of cash from the sale of OncoCyte shares and this capital, alongside the translational research grant application submitted to CIRM, should it be approved, will help support our work in this area. We also intend to seek additional opportunities to obtain non-dilutive backing for this program."

Lineage management will host a conference call and webcast on Thursday, May 7, 2020, at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time to discuss its first quarter 2020 financial and operating results and provide a business update with additional information on the matters in this release. A live webcast of the conference call will be available online in the [Investors](#) section of Lineage's website. Interested parties may access the conference call by dialing (866) 888-8633 from the U.S. and Canada and (636) 812-6629 from elsewhere outside the U.S. and Canada and should request the "Lineage Cell Therapeutics Call". A replay of the webcast will be available on Lineage's website for 30 days and a telephone replay will be available through May 14, 2020, by dialing (855) 859-2056 from the U.S. and Canada and (404) 537-3406 from elsewhere outside the U.S. and Canada and entering conference ID number 7948501.

About VAC

VAC is an allogeneic, or non-patient specific, product candidate platform designed to stimulate patient immune responses to antigens commonly expressed in cancerous cells but not in normal adult cells. VAC product candidates are produced from a pluripotent cell line using a directed differentiation method and are comprised of a population of nonproliferating mature dendritic cells. As the most potent type of antigen presenting cell in the body, dendritic cells instruct our body's immune system to attack and eliminate harmful pathogens and unwanted cells. Because the antigen is loaded exogenously into the dendritic cells prior to administration, VAC is a platform technology that can be modified to carry any antigen, including patient-specific tumor neo-antigens or viral antigens. An earlier VAC program, called VAC1, was comprised of autologous dendritic cells and provided proof-of-concept for VAC2, an allogeneic product candidate.

About CIRM

With \$3 billion in funding and approximately 300 active stem cell programs in its portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality. In response to the crisis caused by the COVID-19 virus, CIRM recently approved emergency funding and the allocation of \$5 million for peer-reviewed regenerative medicine and stem cell research that could quickly advance treatments for COVID-19. The funding would be awarded as part of an expedited approval process. For more information go to www.cirm.ca.gov or follow CIRM on Twitter: [@CIRMnews](https://twitter.com/CIRMnews).

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) VAC2, a cancer immunotherapy of antigen-presenting dendritic cells in Phase 1 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](https://twitter.com/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 development plans with respect to its VAC technology and SARS-Cov-2. 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.

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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

Source: Lineage Cell Therapeutics, Inc.