



Lineage Cell Therapeutics and Cancer Research UK Announce Encouraging Preliminary Phase 1 Study Results With VAC2 for the Treatment of Non-small Cell Lung Cancer

October 13, 2020

- **Potent Induction of Immune Responses Observed with VAC2 Vaccine**
- **Peripheral Antigen-specific Immunogenicity Above 3% Observed at Multiple Timepoints**
- **VAC2 Appears Well Tolerated with No Unexpected Adverse Events**

CARLSBAD, Calif. & LONDON--(BUSINESS WIRE)--Oct. 13, 2020-- [Lineage Cell Therapeutics, Inc.](#) (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs, and [Cancer Research UK](#), the world's leading cancer charity dedicated to saving lives through research, today announced encouraging preliminary results from an ongoing Phase 1 clinical study of [VAC2](#) in non-small cell lung cancer (NSCLC). VAC2 demonstrated remarkably potent induction of immune responses in all patients dosed to date, with high levels of peripheral antigen-specific immunogenicity observed at multiple time points and confirmed by multimer staining. On the basis of these findings, and following completion of the ongoing VAC2 clinical study in NSCLC, Lineage will seek to evaluate VAC2 in combination with therapies considered biologically complementary to VAC2, such as chemotherapy and the immune cell protectant properties offered by anti-PD1 immunotherapy.

Lineage recently conducted an early exercise of its option to acquire data from Cancer Research UK and assumed responsibility for further development of the VAC2 product candidate as well as future development opportunities derived from the VAC platform, while Cancer Research UK's Centre for Drug Development concludes the ongoing clinical study.

"Based on review of all available data, the therapy was safe and well tolerated in all patients. While the safety profile was expected, the immunogenicity data are remarkable and highly provocative," stated Christian Ottensmeier, MD, PhD, FRCP, Professor of Experimental Medicine at the University of Southampton and Chief Investigator on the VAC2 clinical study. "Antigen-reactive pentamer staining data induced by VAC2 suggest that the vaccine is highly potent, inducing significantly higher levels of antigen-specific T cells, compared with that invoked by alternative vaccine approaches, such as DNA- and RNA-based vaccines. From my perspective as an immuno-oncologist these data support rapid phase II testing, focused on clinical benefit."

Brian Culley, Chief Executive Officer of Lineage, said: "Interestingly, one patient experienced a radiological response following chemotherapy subsequent to VAC2 treatment. Although anecdotal and occurring after the patient had completed the VAC2 trial, responses in this setting are rare and support further investigation. Dendritic cells are the most potent antigen-presenting cells in the body and harnessing their power to accurately deliver information about foreign material is re-emerging as an attractive therapeutic modality based on their consistent safety profile and increasing knowledge of how to deploy them in the clinical setting. As a leader in the field of cell therapy, Lineage aims to advance the current VAC2 product candidate and identify ways to expand the VAC platform through internally-owned and externally-partnered antigens."

Dr. Nigel Blackburn, Cancer Research UK's Director of Drug Development, said: "We are pleased to see, after several years of development, the clinical progress that VAC2 has made and the impact it could have for people with lung cancer, which is the third most common cancer in the UK. We are excited to continue our support of the next phase of development of VAC2 and assist with the expansion of those efforts into additional cancers, and other potential areas with significant unmet medical need."

About VAC2

VAC2 is an allogeneic, or non-patient specific, off-the-shelf cancer vaccine product candidate designed to stimulate patient immune responses to an antigen commonly expressed in cancerous cells but not in normal adult cells. VAC2, which is produced from a pluripotent cell technology using a directed differentiation method, is comprised of a population of nonproliferating mature dendritic cells. As the most potent type of antigen presenting cell in the body, dendritic cells instruct the body's immune system to attack and eliminate harmful pathogens and unwanted cells. Because the tumor antigen is loaded exogenously into the dendritic cells prior to administration, VAC2 is a platform technology that can be modified to carry any antigen, including patient-specific tumor neo-antigens or viral antigens. VAC2 is currently being tested in a Phase 1 clinical study in adult patients with non-small cell lung cancer (NSCLC) in the advanced and adjuvant settings (NCT03371485), conducted by Cancer Research UK.

About T Cell Induction

Lopes A, Vandermeulen G, Pr at V. Cancer DNA vaccines: current preclinical and clinical developments and future perspectives. *J Exp Clin Cancer Res.* 2019;38(1):146.; Sebastian M, Schr oder A, Scheel B, et al. A phase I/IIa study of the mRNA-based cancer immunotherapy CV9201 in patients with stage IIIB/IV non-small cell lung cancer. *Cancer Immunology, Immunotherapy* 2019;68(5):799-812.

About Cancer Research UK's Centre for Drug Development

Cancer Research UK has an impressive record of developing novel treatments for cancer. The Cancer Research UK Centre for Drug Development has been pioneering the development of new cancer treatments for 25 years, taking over 140 potential new anti-cancer agents into clinical trials in patients. It currently has a portfolio of 21 new anti-cancer agents in preclinical development, Phase I or early Phase II clinical trials. Six of these new agents have made it to market including temozolomide for brain cancer, abiraterone for prostate cancer and rucaparib for ovarian cancer. Two other drugs are in late development Phase III trials.

About Cancer Research UK's Commercial Partnerships Team

Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research. Cancer Research UK's specialist Commercial Partnerships Team works closely with leading international cancer scientists and their institutes to protect intellectual property arising from their research and to establish links with commercial partners. Cancer Research UK's commercial activity operates through Cancer Research Technology Ltd., a wholly owned subsidiary of Cancer Research UK. It is the legal entity which pursues drug discovery research in themed alliance partnerships and delivers varied commercial partnering arrangements.

About Cancer Research UK

- Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research.
- Cancer Research UK's pioneering work into the prevention, diagnosis and treatment of cancer has helped save millions of lives.
- Cancer Research UK has been at the heart of the progress that has already seen survival in the UK double in the last 40 years.
- Today, 2 in 4 people survive their cancer for at least 10 years. Cancer Research UK's ambition is to accelerate progress so that by 2034, 3 in 4 people will survive their cancer for at least 10 years.
- Cancer Research UK supports research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses.
- Together with its partners and supporters, Cancer Research UK's vision is to bring forward the day when all cancers are cured.

For further information about Cancer Research UK's work or to find out how to support the charity, please call 0300 123 1022 or visit www.cancerresearchuk.org. Follow us on [Twitter](#) and [Facebook](#).

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 and in preclinical development for additional cancers and as a vaccine against infectious diseases, including SARS-CoV-2, the virus which causes COVID-19. 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 plans to advance the VAC2 platform. 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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