



Lineage and Cancer Research UK Announce Completion of Patient Enrollment in Phase 1 Clinical Study of VAC2 for the Treatment of Non-small Cell Lung Cancer

April 13, 2022

CARLSBAD, Calif.--(BUSINESS WIRE)--Apr. 13, 2022-- [Lineage Cell Therapeutics, Inc.](#) (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, announced today that [Cancer Research UK](#) recently completed patient enrollment in the ongoing Phase 1 clinical trial of VAC2, an allogeneic cancer vaccine product candidate, for the treatment of non-small cell lung cancer ("NSCLC"). Under the terms of an existing agreement, Cancer Research UK will complete the ongoing clinical trial and Lineage has now assumed responsibility for further clinical development of the VAC2 product candidate and any future development opportunities derived from the VAC platform.

"We are pleased that Cancer Research UK has successfully completed patient enrollment in the VAC2 Phase 1 clinical study and overcame substantial challenges stemming from the COVID pandemic. We look forward to initial clinical results from this study being available later this year," stated Brian M. Culley, Lineage CEO. "Clinical data previously collected by Cancer Research UK demonstrated peripheral immunogenicity in patients with NSCLC treated with VAC2, providing support to the underlying mechanism of using allogeneic dendritic cells to present tumor-associated antigens to the body's immune system. Simultaneous with Cancer Research UK efforts to complete enrollment in the current study, the focus at Lineage has been on making improvements and modernizations to the VAC manufacturing process, an approach which we similarly employed in the development of OpRegen. We believe our focus on manufacturing will help prepare VAC2 for additional clinical trials and provide a competitive advantage for any future VAC programs which we advance, either alone or through alliances. With Cancer Research UK having completed enrollment of the current study, the team at Lineage also has begun work towards the submission of an Investigational New Drug Application for clinical testing of VAC2 in the U.S., which we anticipate submitting to the FDA later this year."

Dr. Nigel Blackburn, Director of Cancer Research UK's Centre for Drug Development, added: "We are delighted to see that this innovative VAC2 program has reached such an important milestone in its development and are extremely proud to have played an important role in establishing its tolerability in lung cancer patients. We look forward to seeing Lineage advance VAC2 under their leadership in the future."

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 could be modified to carry selected antigens, including patient-specific tumor neo-antigens or viral antigens. VAC2 is currently being tested in a Phase 1 study in adult patients with NSCLC in the advanced and adjuvant settings (NCT03371485), conducted by Cancer Research UK.

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 receives no funding from the UK government for its life-saving research. Every step it makes towards beating cancer relies on vital donations from the public.
- 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 four 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, which is now being [developed](#) under a worldwide collaboration with Roche and Genentech, a member of the Roche Group; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; (iii) VAC2, a dendritic cell therapy produced from Lineage's VAC technology platform for immuno-oncology and infectious disease, currently in Phase 1 clinical development for the treatment of non-small cell lung cancer and (iv) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy. 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," "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. Such statements include, but are not limited to, statements relating to the efficacy of using allogeneic dendritic cells to present tumor-associated antigens to the body's immune system the collaboration and license agreement with Roche and Genentech and activities expected to occur thereunder, the broad potential for Lineage's regenerative medicine platform as well as the VAC technology platform, and Lineage's ability to expand the same; the projected timing of milestones of future studies, including their initiation and completion, projected manufacturing plans and improvements; the potential for Lineage's investigational allogeneic cell therapies to generate clinical outcomes beyond the reach of traditional methods and provide safe and effective treatment for multiple, diverse serious or life threatening conditions. 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 risk that competing alternative therapies may adversely impact the commercial potential of OpRegen, which could materially adversely affect the milestone and royalty payments payable to Lineage under the collaboration and license agreement, the risk that Roche and Genentech may not be successful in completing further clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction, the risk that Lineage might not succeed in developing products and technologies that are useful in medicine and demonstrate the requisite safety and efficacy to achieve regulatory approval in accordance with its projected timing, or at all; the risk that Lineage may not be able to manufacture sufficient clinical and, if approved, commercial quantities of its product candidates in accordance with current good manufacturing practice; the risks related to Lineage's dependence on other third parties, and Lineage's ability to establish and maintain its collaborations with these third parties; the risk that government-imposed bans or restrictions and religious, moral, and ethical concerns about the use of hES cells could prevent Lineage or its partners from developing and successfully marketing its stem cell product candidates; the risk that Lineage's intellectual property may be insufficient to protect its products; the risk that the COVID-19 pandemic or geopolitical events may directly or indirectly cause significant delays in and substantially increase the cost of development of Lineage's product candidates, as well as heighten other risks and uncertainties related to Lineage's business and operations; risks and uncertainties inherent in Lineage's business and other risks discussed in Lineage's filings with the Securities and Exchange Commission (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 most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the SEC 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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Source: Lineage Cell Therapeutics, Inc.