Lineage Announces Launch of Phase 2a Study by Genentech of RG6501 (OpRegen®) in Patients With Geographic Atrophy Secondary to Age-Related Macular Degeneration

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CARLSBAD, Calif.--(BUSINESS WIRE)--Nov. 28, 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 its partner Genentech, a member of the Roche Group, has launched a Phase 2a, multicenter, open-label, single arm clinical study of RG6501 (OpRegen), a retinal pigment epithelial cell therapy. The study is intended to optimize subretinal surgical delivery and evaluate the safety and activity of OpRegen in approximately 30, and up to 60 patients with geographic atrophy (GA) secondary to age-related macular degeneration. The primary objectives of the study are to evaluate (i) the proportion of patients with subretinal surgical delivery of OpRegen to target regions under the retina, and (ii) to evaluate the safety of subretinal surgical delivery of OpRegen as measured by the incidence and severity of procedure-related adverse events at 3 months following surgery. A key secondary objective is to evaluate the proportion of patients with qualitative improvement in retinal structure, as determined by Optical Coherence Tomography (SD-OCT) imaging, within 3 months following surgery. RG6501 (OpRegen) is currently being developed under an exclusive worldwide collaboration between Lineage, Roche and Genentech.

“In our Phase 1/2a clinical trial, RG6501 (OpRegen) demonstrated the potential to slow, stop, or reverse the progression of GA in patients with GA. These results can be maintained beyond one year following a one-time, approximately 30-minute outpatient procedure,” stated Brian M. Culley, Lineage CEO. “We are excited that Roche and Genentech are advancing the OpRegen program in a larger clinical study and will seek not only to optimize and potentially improve its delivery, but also confirm safety and activity of OpRegen in this patient population. We expect the findings from this Phase 2a study will be highly informative and may increase the probability of success in any future larger, comparative trials.”

“We are excited for the launch of this Phase 2a study, where one of the key objectives is to optimize the delivery of OpRegen to achieve the best outcomes,” stated Seppi Lin, Vice President of OMNI Early Clinical Development at Genentech. “This study will provide key insights for the future development of the OpRegen program. Geographic Atrophy (GA) secondary to AMD is a disease area of high unmet need with no approved therapies, and we are committed to developing effective and innovative medicines for patients with serious eye diseases.”

About the Phase 2a Study

The planned Phase 2a clinical study is a multicenter, open-label, single arm study to optimize subretinal surgical delivery and to evaluate the safety and activity of OpRegen in patients with GA secondary to AMD. Approximately 30 and up to 60 patients may be enrolled across multiple sites and will receive OpRegen administered as a single subretinal injection to one eye with impaired vision. Study treatment will consist of a single subretinal injection of OpRegen at a dose of up to approximately 200,000 cells delivered to target areas of GA in the study eye.

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About Geographic Atrophy

Geographic atrophy (GA) is an advanced form of age-related macular degeneration (AMD) characterized by severe loss of visual function. GA is a leading cause of adult blindness in the developed world, affecting at least 5 million people globally. There are two forms of advanced AMD: neovascular AMD and GA. GA and neovascular AMD can occur simultaneously in the same eye, and patients treated for neovascular AMD may still go on to develop GA. GA typically affects both eyes. There are currently no U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) approved treatment options available for patients with GA.

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 and preclinical programs are in markets with billion dollar opportunities and include five allogeneic (“off-the-shelf”) product candidates: (i) OpRegen, a retinal pigment epithelial cell therapy in Phase 2a development for the treatment of geographic atrophy secondary to age-related macular degeneration, is 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; (iv) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; and (v) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage. 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: our collaboration and license agreement with Roche and Genentech and the timing of anticipated FDA interactions; the potential of RG6501 (OpRegen) to be a safe, effective and durable, one-time treatment for geographic atrophy secondary to age related macular degeneration; the significance of this Phase 2a study, including the potential that it will be informative or increase the potential of success in future larger, comparative trials; and preclinical activities, clinical trials, and clinical data updates related to our programs. 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 following risks: that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; that competing alternative therapies may adversely impact the commercial potential of OpRegen; that Roche and Genentech may not successfully advance OpRegen or be successful in completing further clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction; that Lineage may not be able to manufacture sufficient clinical quantities of its product candidates in accordance with current good manufacturing practice; and those 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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