RG6501 (OpRegen®) Phase 1/2a Results Will Be Featured at 2024 Angiogenesis Exudation and Degeneration Meeting in Presentation by Allen Ho, MD, FACS, FASRS

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CARLSBAD, Calif.--(BUSINESS WIRE)--Jan. 16, 2024-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today announced that results showing retinal structure improvements with RG6501(OpRegen) from a Phase 1/2a clinical study (ClinicalTrials.gov Identifier: NCT02286089) in geographic atrophy (GA) secondary to advanced age-related macular degeneration (AMD), will be presented at the 2024 Angiogenesis, Exudation, and Degeneration Meeting. The virtual meeting will be held February 3, 2024, and is sponsored by the University of Miami Health System Bascom Palmer Eye Institute. The presentation, *"Retinal Structure Improvements with OpRegen RPE Cell Therapy in a Phase I/IIa Study in Geographic Atrophy,"* will be presented by Allen Ho, MD, FACS, FASRS, Co-Director, Wills Eye Retina Service and Director, Retina Research, Wills Eye Hospital on behalf of Roche and Genentech, a member of the Roche Group.

About OpRegen

RG6501 (OpRegen) is a suspension of human allogeneic retinal pigment epithelial (RPE) cells currently in development for the treatment of GA secondary to AMD. OpRegen subretinal delivery has the potential to counteract RPE cell loss in areas of GA lesions by supporting retinal cell health and improving retinal structure and function. It is being developed under an exclusive worldwide collaboration between Lineage, and Roche and Genentech, a member of the Roche Group, and is currently being evaluated in a Phase 2a clinical study in patients with GA secondary to AMD (ClinicalTrials.gov Identifier: NCT05626114).

About Angiogenesis

The 21st Annual Angiogenesis meeting, entitled Angiogenesis, Exudation, and Degeneration 2024, will be held virtually on February 3, 2024. The program will feature an exceptional group of basic scientists, clinicians, and healthcare experts, all focused on understanding and treating neovascular, exudative, and degenerative diseases of the eye. The program will highlight the revolutionary pharmacotherapies now in development and clinical practice for the management of neovascular AMD, macular edema, diabetic retinopathy, retinopathy of prematurity, and inherited retinal degenerations with a special emphasis on the present and future financial impact of these drugs on clinical practices and Medicare. Angiogenesis 2024 follows the tradition of excellence established by Bascom Palmer's widely acclaimed Angiogenesis programs between 2004 and 2023. Designed for retina specialists, general ophthalmologists and researchers, the current program will review the latest in imaging, translational research, and clinical trials with an emphasis on how these results will impact clinical ophthalmology. For more information visit: https://umiamihealth.org/bascom-palmer-eye-institute/healthcare-professionals/continuing-medical-education/angiogenesis.

About the OpRegen Phase 1/2a Study

The Phase 1/2a study is an open-label, single-arm, multi-center, dose-escalation trial evaluating a single administration of OpRegen delivered subretinally in patients with bilateral GA secondary to AMD. Twenty-four patients were enrolled into 4 cohorts. The first 3 cohorts enrolled only legally blind patients with a best corrected visual acuity (BCVA) of 20/200 or worse. The fourth cohort enrolled 12 patients with impaired vision (BCVA from 20/65 to 20/250 with smaller mean areas of GA). Cohort 4 also included patients treated with a new "thaw-and-inject" formulation of OpRegen, which can be shipped directly to sites and used immediately upon thawing, removing the complications and logistics of having to use a dose preparation facility. The primary objective of the study was to evaluate the safety and tolerability of OpRegen as assessed by the incidence and frequency of treatment-emergent adverse events. Secondary objectives include evaluating the preliminary activity of OpRegen treatment by assessing the changes in ophthalmological parameters measured by various methods of primary clinical relevance.

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.

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: the potential therapeutic benefits of OpRegen in patients with GA secondary to AMD. 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 studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; 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; 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 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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