RG6501 (OpRegen®) Phase 1/2a Clinical Study 36 Month Results to Be Featured at Clinical Trials at the Summit 2025

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CARLSBAD, Calif.--(BUSINESS WIRE)--May 12, 2025-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for serious neurological conditions, today announced that 36-month results from patients enrolled in a Phase 1/2a clinical study (ClinicalTrials.gov Identifier: NCT02286089) of RG6501 (OpRegen) in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD), will be presented at Clinical Trials at the Summit (CTS) 2025. CTS will be held June 20 - 21, 2025, and brings together a diverse group of experts from around the world to discuss ongoing clinical trials and the latest data, all with the goal of achieving advances in vitreoretinal care. The presentation, *"OpRegen® Retinal Pigment Epithelium (RPE) Cell Therapy for Patients with Geographic Atrophy (GA): Month 36 Results from the Phase 1/2a Trial,"* will be presented by Christopher D. Riemann, M.D., Vitreoretinal Surgeon and Fellowship Director, Cincinnati Eye Institute (CEI) and University of Cincinnati School of Medicine, on behalf of Roche and Genentech, a member of the Roche Group.

About OpRegen

OpRegen (RG6501) is a suspension of allogeneic retinal pigment epithelial (RPE) cells currently in development for the treatment of GA secondary to AMD. Subretinal delivery of OpRegen has the potential to counteract RPE cell loss in GA by supporting retinal cell health and improving retinal structure and function. OpRegen 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 Clinical Trials at The Summit (CTS) 2025

Clinical Trials at the Summit (CTS) 2025 brings together a diverse group of experts from around the world to discuss ongoing clinical trials and the latest data, all with the goal of achieving advances in vitreoretinal care. This program will explore the partnerships and strategies required to design and execute effective clinical trials. CTS was founded by Arshad M. Khanani, MD, MA, Director of Clinical Research at Sierra Eye Associates, and is Co-Chaired by Jeffrey S. Heier, MD, Ophthalmic Consultants of Boston and Peter K. Kaiser, MD, Cole Eye Institute, Cleveland Clinic. CTS is an invitation-only, in-person meeting where participants will have the exclusive opportunity to interact with the top national and international key opinion leaders in retina at the Fontainebleau Las Vegas. For more information visit: www. https://www.ctsretina.org/.

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

GA is an advanced form of 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, "off-the-shelf," cell therapies to address unmet medical needs. Lineage's programs are based on its proprietary cell-based technology platform and associated development and manufacturing capabilities. From this platform, Lineage designs, develops, manufactures, and tests specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. These cells are created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages are transplanted into patients in an effort to replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and to restore or augment the patient's functional activity. Lineage's neuroscience focused pipeline currently includes: (i) OpRegen, a retinal pigment epithelial cell therapy in Phase 2a development under a worldwide collaboration with Roche and Genentech, a member of the Roche Group, for the treatment of geographic atrophy secondary to age-related macular degeneration; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of spinal cord injuries; (iii) ReSonance™ (ANP1), an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; (iv) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage; and (v) RND1, a novel hypoimmune induced pluripotent stem cell line being developed under a gene editing partnership. For more information, please visit www.lineagecell.com or follow the company on X/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 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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