OpRegen® (RG6501) Phase 1/2a Results to Be Featured at International Society for Stem Cell Research (ISSCR) 2024 Copenhagen International Symposium

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CARLSBAD, Calif.--(BUSINESS WIRE)--Sep. 25, 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 Brian M. Culley, Lineage's Chief Executive Officer, will be presenting at the International Society for Stem Cell Research (ISSCR) 2024 Copenhagen International Symposium, PSC-Derived Cell Therapies: Clinical Advances, NextGen Technologies, and the Path to Success. Mr. Culley has been invited to participate as part of a panel entitled "Clinical Trial Updates: PSC-Derived Therapies of the Eye," on Wednesday, October 2nd, 2024, from 10:30 am to 12 pm CEST. The panel is being chaired by Kapil Bharti, Ph.D., Senior Investigator and Scientific Director, Ocular and Stem Cell Translational Research Section at the National Eye Institute (NEI), and will also feature executive presenters from Vision Care and Regenerative Patch Technologies, Inc. The 2024 Copenhagen International Symposium will take place October 2 – 4, 2024 at The Black Diamond, Royal Danish Library, Copenhagen, Denmark, and is being presented by the ISSCR in partnership with Novo Nordisk.

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, 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).

The 2024 Copenhagen International Symposium presentation, "*OpRegen®: A Suspension Of Allogeneic Retinal Pigment Epithelial (RPE) Cells In Patients With Geographic Atrophy (GA) Secondary To Age-Related Macular Degeneration (AMD)*," will be available on the Events and Presentations section of Lineage's website, following the conclusion of the ISSCR panel presentation.

About The 2024 Copenhagen International Symposium: PSC-Derived Cell Therapies: Clinical Advances, NextGen Technologies, and the Path to Success

Pluripotent stem cell-derived cell therapies are accelerating rapidly into clinical trials. The ISSCR, in partnership with Novo Nordisk, is pleased to invite attendees to Copenhagen, Denmark in October 2024 for an event that will gather pioneers at the forefront of ESC and iPSC-derived cell therapies. Here, world-renowned scientists and innovators will share the latest updates on ongoing clinical trials, as well as groundbreaking platforms and technologies that will revolutionize the next generation of cell therapies for devastating and intractable diseases. For more information visit https://www.isscr.org/upcoming-programs/2024-copenhagen-international-symposium/#program or follow the organization on X/Twitter: @ISSCR.

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 in collaboration with Eterna Therapeutics Inc. 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. Lineage’s forward-looking statements are based upon its current expectations and beliefs and involve assumptions that may never materialize or may prove to be incorrect. 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 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 OpRegen may never be proven to provide durable anatomical functional improvements in dry-AMD patients, that the ongoing Israel-Hamas war may materially and adversely impact our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, all of which are conducted by our subsidiary in Jerusalem, Israel; 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). 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. All forward-looking statements are expressly qualified in their entirety by these cautionary statements.

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