



Lineage Cell Therapeutics to Present OpRegen® Data at International Society for Stem Cell Research (ISSCR) 2020 Virtual Annual Meeting

June 24, 2020

CARLSBAD, Calif.--(BUSINESS WIRE)--Jun. 24, 2020-- [Lineage Cell Therapeutics, Inc.](#) (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs, today announced that interim results from its Phase 1/2a clinical study of its lead product candidate, [OpRegen®](#), a retinal pigment epithelium (RPE) cell transplant therapy currently in development for the treatment of dry age-related macular degeneration (dry AMD), will be presented at the [International Society for Stem Cell Research \(ISSCR\) 2020 Annual Meeting](#), which will be held virtually June 23 to June 27, 2020. The abstract presentation, entitled, "Phase I/IIa Clinical Trial of Stem Cell (hESC)-Derived Retinal Pigmented Epithelium (RPE, OpRegen) Transplantation in Advanced Dry Form Age-Related Macular Degeneration (AMD): Interim Results", will be presented on Saturday June 27, 2020 by [Benjamin F. Reubinoff, M.D., Ph.D.](#), Chairman and Professor at Hadassah Medical Center, Jerusalem, Israel. The presentation will provide data from patient cohorts 1 through 4 of the clinical study.

About ISSCR 2020

The International Society for Stem Cell Research has transformed its annual scientific meeting into a virtual experience, bringing the global stem cell community together to share knowledge, collaborate, and network. The ISSCR 2020 Virtual Meeting, co-sponsored by the Harvard Stem Cell Institute (HSCI), will deliver a comprehensive scientific education program that includes plenaries featuring world-renowned scientists in the field. For more information, please visit www.isscr.org or follow the association on Twitter [@ISSCR](#).

About Dry AMD

Dry age-related macular degeneration (AMD) is a leading cause of adult blindness in the developed world. There are two forms of AMD: wet AMD and dry AMD. Dry AMD is the more common of the two types, accounting for approximately 85-90% of cases. Wet AMD is the less common of the two types, accounting for approximately 10-15% of cases. Global sales of the two leading wet AMD therapies were in excess of \$10 billion in 2019. Nearly all cases of wet AMD begin as dry AMD. Dry AMD 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 dry AMD.

About OpRegen

OpRegen is currently being evaluated a Phase 1/2a open-label, dose escalation safety and efficacy study of a single injection of human retinal pigment epithelium cells derived from an established pluripotent cell line and transplanted subretinally in patients with advanced dry AMD with GA. The study will enroll patients into 4 cohorts, with 18 of 21 expected patients enrolled to date. The first 3 cohorts enrolled only legally blind patients with best corrected visual acuity (BCVA) of 20/200 or worse. The fourth cohort, which is currently enrolling, will include patients with vision as high as 20/64. Cohort 4 also includes 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 is to evaluate the safety and tolerability of OpRegen as assessed by the incidence and frequency of treatment emergent adverse events. Secondary objectives are to evaluate the preliminary efficacy of OpRegen treatment by assessing the changes in ophthalmological parameters measured by various methods of primary clinical relevance. Additionally, for the patients in Cohort 4 that receive subretinal delivery of OpRegen utilizing Gyroscope Therapeutics' Orbit Subretinal Delivery System (Orbit SDS), objectives will include the evaluation of the safety of delivery of OpRegen using the Orbit SDS.

Recently, Lineage [reported](#) the first known finding of retinal tissue regeneration in a patient receiving OpRegen for the treatment of atrophic dry AMD. This unprecedented finding supports the view that dry AMD is not an irreversible, degenerative condition and that some portion of diseased retinal tissue may be recoverable in atrophic end-stage disease patients. These findings were initially observed by an independent external advisor using multiple imaging technologies and were subsequently confirmed by the reading center and additional experts in the field of retinal imaging. The Company also has [observed](#) evidence of benefit in other patients, including increases in Best Corrected Visual Acuity (BCVA), reduction in the growth of GA, and increases in reading speed.

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 three 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, a leading cause of blindness in the developed world; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; and (iii) VAC, an allogeneic dendritic cell therapy platform for immuno-oncology and infectious disease, currently in clinical development for the treatment of non-small cell lung cancer and in preclinical development for additional cancers and as a vaccine against infectious diseases, including SARS-CoV-2, the virus which causes COVID-19. For more information, please visit www.lineagecell.com or follow the Company on Twitter [@LineageCell](#).

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