Lineage Cell Therapeutics Announces Extension of OpRegen® Development Grant From Israel Innovation Authority

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CARLSBAD, Calif.--(BUSINESS WIRE)--Jul. 6, 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 as a result of continued clinical progress, the Israel Innovation Authority (IIA) has extended its previously awarded development grant in support of OpRegen®, the Company's retinal pigment epithelium (RPE) cell transplant therapy in development for the treatment of dry age-related macular degeneration (AMD). The research & development grant of up to 9 million Israeli New Shekels (approximately $2.5 million) was awarded in 2019 by the IIA and has been extended for use through June 2021 based on promising clinical data from the ongoing Phase 1/2a clinical study of OpRegen. The IIA has provided annual grants totaling approximately $16 million for the development of the OpRegen program so far.

"We are pleased that the IIA has elected to extend its financial support based on the positive momentum and clinical achievements we have demonstrated with our OpRegen program to date," stated Brian M. Culley, Lineage CEO. "We continue to generate promising data supporting the use of our RPE cells in dry AMD with GA. Notably, after moving into patients with less advanced disease, we announced the first known finding of retinal tissue regeneration alongside reductions in the growth of geographic atrophy, and improvements in visual acuity and reading speeds in some patients. We recently resumed patient enrollment in our OpRegen study, and our immediate efforts are focused on treating and monitoring the final three patients in Cohort 4 and utilizing these data to direct our clinical, regulatory, and partnership discussions for the program. The partnerships we have built with notable institutions like the IIA, the California Institute for Regenerative Medicine, and Cancer Research UK, provide not only capital, but also external validation of our programs, and we are working to strengthen and expand these alliances as we move forward. Concurrently, we are actively looking to identify new partnerships to help support the development of all of our programs."

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 The Israel Innovation Authority

The Israel Innovation Authority, an independent publicly funded agency, was created to provide a variety of practical tools and funding platforms aimed at effectively addressing the dynamic and changing needs of the local and international innovation ecosystems. This includes early-stage entrepreneurs, mature companies developing new products or manufacturing processes, academic groups seeking to transfer their ideas to the market, global corporations interested in collaborating with Israeli technology, Israeli companies seeking new markets abroad and traditional factories and plants seeking to incorporate innovative and advanced manufacturing into their businesses. More information is available at: https://innovationisrael.org.il/en/contentpage/israel-innovation-authority.

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 the 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.

OpRegen is a registered trademark of Cell Cure Neurosciences Ltd., a majority-owned subsidiary of Lineage Cell Therapeutics, Inc.

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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Lineage Cell Therapeutics, Inc. IR
Ioana C. Hone
(ir@lineagecell.com)
(442) 287-8963

Solebury Trout IR
Gitanjali Jain Ogawa
(Gogawa@troutgroup.com)
(646) 378-2949

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