Lineage Cell Therapeutics and AgeX Therapeutics Announce Issuance of U.S. Patent for Method of Generating Induced Pluripotent Stem Cells

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CARLSBAD, Calif.--(BUSINESS WIRE)--Dec. 10, 2019-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX) and AgeX Therapeutics, Inc. (NYSE American: AGE), announced today that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 10,501,723, entitled "Methods of Reprogramming Animal Somatic Cells" covering what is commonly designated "induced Pluripotent Stem (iPS) cells." The issued claims include methods to manufacture pluripotent cells capable of becoming any cell in the body. The patent has an early priority date, having been filed before the first scientific publication of Shinya Yamanaka, for which he won the Nobel Prize for Physiology or Medicine in 2012.

"The issuance of this patent highlights Lineage's dominant position in the field of cell therapy," stated Brian M. Culley, CEO of Lineage. "Our efforts to develop new treatments rely on well-characterized and NIH-approved human cell lines. These lines are not genetically manipulated, which avoids the safety concerns associated with genetic aberrations arising from the creation of iPS cells. We believe the Lineage cell lines provide the safest option for our current clinical-stage programs, particularly in immune-privileged anatomical sites such as the eye (OpRegen® for the treatment of dry AMD) and spinal cord (OPC1, for the treatment of spinal cord injury). However, the vast intellectual property estate which underlies our cell therapy platform has never been limited to these particular cell lines. As one example, this newly-issued patent provides us with proprietary methods for producing induced pluripotent stem cells, or, as it was practiced by us prior to Yamanaka, Analytical Reprogramming Technology (ART). In certain settings, an ART/iPS approach might offer important advantages, such as for an autologous treatment or when the selection of preferential attributes from a series of iPS lines is desirable. Questions as to which stem cell technology is preferred ultimately will be answered by clinical safety and efficacy and likely will be indication-specific, so we believe it is in the best interest of our shareholders to generate patented technology which enables us to pursue programs in either or both formats which we believe will ensure the highest probability of success."

"This patent broadly describes multiple techniques for reprogramming cells of the body back to the all-powerful stem cell state," said Dr. Michael D. West, CEO of AgeX and first inventor on the patent. "Perhaps more significantly, it includes certain factors that address some of the difficulties currently encountered with iPS cells. It also reflects the foundational work our scientists have undertaken to apply reprogramming technology to age-reversal, specifically, induced Tissue Regeneration (iTR) which is currently a focus of AgeX product development."

Induced Pluripotent Stem Cells (iPS) are typically derived from adult skin or blood cells which have been "reprogrammed" or "induced" to retrace their developmental age and regain the potential to form all of the young cell and tissue types of the body. In 2010 inventors of the -723 patent issued today demonstrated that this reversal of developmental aging even extended to the telomere clock of cell aging. This reprogramming technology provides an alternate source of starting material for the manufacture of potentially any type of human cell needed for therapeutic purposes. Because iPSCs can be derived directly from adult tissues, they can be used to generate pluripotent cells from patients with known genetic abnormalities for drug discovery or as an alternative source of cell types for regenerative therapies.

U.S. Patent No. 10,501,723, entitled "Methods of Reprogramming Animal Somatic Cells" was assigned to Advanced Cell Technology of Marlborough, Massachusetts (now Astellas Institute for Regenerative Medicine) and licensed to Lineage and sublicensed to AgeX Therapeutics for defined fields of use. Inventors of the patent include Michael D. West, CEO of AgeX and previous CEO of Advanced Cell Technology, Karen B. Chapman, Ph.D., and Roy Geoffrey Sargent, Ph.D.

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 proprietary cell-based therapy platform and associated 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 either to 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 assets include (i) OpRegen®, a retinal pigment epithelium transplant therapy in Phase I/IIa 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 I/IIa development for the treatment of acute spinal cord injuries; and (iii) VAC2, an allogeneic cancer immunotherapy of antigen-presenting dendritic cells currently in Phase I development for the treatment of non-small cell lung cancer. Lineage is also evaluating potential partnership opportunities for Renevia®, a facial aesthetics product that was recently granted a Conformité Européenne (CE) Mark. For more information, please visit www.lineagecell.com or follow the Company on Twitter @LineageCell.

About AgeX Therapeutics

AgeX Therapeutics, Inc. (NYSE American: AGE) is focused on developing and commercializing innovative therapeutics for human aging. Its PureStem® and UniverCyte ™manufacturing and immunotolerance technologies are designed to work together to generate highly-defined, universal, allogeneic, off-the-shelf pluripotent stem cell-derived young cells of any type for application in a variety of diseases with a high unmet medical need. AgeX has two preclinical cell therapy programs: AGEX-VASC1 (vascular progenitor cells) for tissue ischemia and AGEX-BAT1 (brown fat cells) for Type II diabetes. AgeX's revolutionary longevity platform induced Tissue Regeneration (iTR™) aims to unlock cellular immortality and regenerative capacity to reverse age-related changes within tissues. AGEX-iTR1547 is an iTR-based formulation in preclinical development. HyStem® is AgeX's delivery technology to stably engraft PureStem cell therapies in the body. AgeX is developing its core product pipeline for use in the clinic to extend human healthspan and is seeking opportunities to establish licensing and collaboration agreements around its broad IP estate and proprietary technology platforms. For more information, please visit www.agexinc.com or connect with the company on Twitter, LinkedIn, Facebook, and YouTube.

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,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “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, Lineage’s exploration of alternative cell therapy platforms. 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 risks and uncertainties inherent in Lineage’s business and other risks in Lineage’s filings with the Securities and Exchange Commission (the 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 Annual Report on Form 10-K filed with the SEC on March 14, 2019 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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Source: Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics, Inc. IR
Ioana C. Hone
(ir@lineagecell.com)
(510) 871-4188

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