Lineage Announces Initiation of Development Activities for Hypoimmune Pluripotent Cell Line for Neurology Indications Under Partnership With Eterna Therapeutics

September 6, 2023

CARLSBAD, Calif.--(BUSINESS WIRE)--Sep. 6, 2023-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies to replace and restore specific cell types of the human body, today announced the initiation of certain development activities to generate a novel hypoimmune induced pluripotent stem cell (iPSC) line under the Company's exclusive option and license agreement (the "Agreement") with Eterna Therapeutics Inc. ("Eterna"). This marks the next step under the strategic collaboration announced in February 2023, under which Eterna is developing innovative engineered hypoimmune iPSC lines that Lineage will evaluate for differentiation into cell transplant product candidates for central nervous system (CNS) diseases and other neurology indications. Since announcing the deal earlier this year, Lineage has evaluated its development strategy with a group of leading neurology experts in the U.S. and abroad. As a result of these and other discussions, and an assessment of the competitive landscape, Lineage finalized its selection of specific gene edits for the initial cell lines to be developed by Eterna. The edits include: the targeted deletion of the B2M gene, designed to reduce the immunogenicity of product candidates derived from the lines by inhibiting rejection by CD8+ T cells; the targeted insertion of the HLA-E gene, designed to overexpress HLA-E and prevent the allogeneic NK cell response; and a third undisclosed edit intended to confer clinical differentiation and a competitive advantage in the applicable indications. Lineage expects that these edits would expand the edited cell lines' overall utility, including for non-immune privileged or non-human leukocyte antigen (HLA) matched indications and will further differentiate the cell line from others currently in use by competitors.

"Our partnership with Eterna reflects an important step in a corporate strategy intended to capitalize on our existing process development capabilities by combining them with cutting-edge cell engineering and editing technologies, to create novel and potentially superior product profiles," stated Brian M. Culley, Chief Executive Officer of Lineage. "This collaboration reflects our effort to broaden the application of our cell therapy platform and our plans for future success in this growing field. We look forward to leveraging our expertise to develop innovative cell transplant therapies that have the potential to transform the treatment of a wide range of diseases by capitalizing on the convergence of directed cell differentiation and manufacturing with modern gene editing technology."

"We are excited to move forward with the next phase of our partnership with Lineage," said Matt Angel, Ph.D., Chief Executive Officer and President of Eterna. "We believe that pluripotent cell therapies have the potential to significantly outperform traditional approaches in certain settings and that this milestone highlights Eterna's capabilities for generating novel gene-edited iPSC lines using our mRNA cell engineering platform."

Under the Agreement, Eterna plans to conduct certain gene-editing activities and provide materials to Lineage for evaluation and Lineage will make payments to Eterna in connection with Eterna's successful development and delivery to Lineage of certain materials. The Agreement provides Lineage an option to obtain an exclusive license to utilize and sublicense the novel gene-edited cell lines developed by Eterna for preclinical, clinical, and commercial purposes in the field of CNS diseases. Eterna is the exclusive licensee of the key intellectual property underlying this collaboration from its discovery partner Factor Bioscience.

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 and preclinical programs are in markets with billion dollar opportunities and include five allogeneic ("off-the-shelf") product candidates: (i) OpRegen ®, a retinal pigment epithelial cell therapy in Phase 2a development for the treatment of geographic atrophy secondary to age-related macular degeneration, is being developed under a worldwide collaboration with Roche and Genentech, a member of the Roche Group; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; (iii) VAC2, a dendritic cell therapy produced from Lineage's VAC technology platform for immuno-oncology and infectious disease, currently in Phase 1 clinical development for the treatment of non-small cell lung cancer; (iv) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; and (v) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage. For more information, please visit www.lineagecell.com or follow the company on Twitter @LineageCell.

About Eterna Therapeutics Inc.

Eterna Therapeutics is a life science company committed to realizing the potential of mRNA cell engineering to provide patients with transformational new medicines. Eterna has in-licensed a portfolio of over 130 patents covering key mRNA cell engineering technologies, including technologies for mRNA cell reprogramming, mRNA gene editing, the NoveSlice™ and UltraSlice™ gene-editing proteins, and the ToRNAdo™ mRNA delivery syste from Factor Bioscience. NoveSlice™, UltraSlice™, and ToRNAdo™ are trademarks of Factor Bioscience. For more information, please vis www.eternatx.com.

About Factor Bioscience Inc.

Founded in 2011, Factor Bioscience develops technologies for engineering cells to advance the study and treatment of disease. Factor's gene-editing technologies enable the precise deletion, insertion, and repair of DNA sequences in living cells to correct disease-causing mutations, make cells resistant to infection and degenerative disease, modulate the expression of immunoregulatory proteins to enable the generation of durable allogeneic cell therapies, and engineer immune cells to more effectively fight cancer. Factor's cell-reprogramming technologies enable the generation of clonal lines of pluripotent stem cells that can be expanded and differentiated into any desired cell type for the development of regenerative cell therapies. For

more information, visit www.factorbio.com.

Lineage Cell Therapeutics 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: our plans to develop potential new cell lines into differentiated cell transplant therapies and potential product candidates, and the potential indications thereof, and that those product candidates may be superior to alternate therapies, including as a result of the Agreement with Eterna; our expectations regarding the utility of edited cell lines, the effect of such cells lines on our overall technology, and any related clinical activities; our ability to differentiate a cell line from those of competitors, to broaden our overall capabilities, and to develop treatments that are differentiated from our competitors as a result of the Agreement. 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 Lineage or Eterna may fail to fully perform under the Agreement or that Lineage, in its sole discretion, may elect not to exercise its license under the Agreement; that the potential benefits of the Agreement, including the potential development of new cell lines into new product candidates, or the success of those product candidates, may not be realized; 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 and subsequent Quarterly Report on Form 10-Q 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230906418784/en/

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

LifeSci Advisors
Daniel Ferry
(daniel@lifesciadvisors.com)
(617) 430-7576

Russo Partners – Media Relations
Nic Johnson or David Schull
(Nic.johnson@russopartnersllc.com)
(David.schull@russopartnersllc.com)
(212) 845-4242

Source: Lineage Cell Therapeutics, Inc.