Lineage Cell Therapeutics Initiates Cell Transplant Program In Type 1 Diabetes

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Initial Program Focus Will Be On Addressing Manufacturing Scale

CARLSBAD, Calif.--(BUSINESS WIRE)--Sep. 8, 2025-- Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel allogeneic, or “off the shelf”, cell therapies for serious medical conditions, today announced the initiation of a new islet cell transplant program in Type 1 Diabetes (T1D). Specifically, the company aims to deploy its manufacturing capability to address the issue of large-scale production of islet cells, with the initial goal of establishing a production modality that can support the entire production process in a dynamic culturing system, potentially solving a major hurdle to commercialization of islet cell therapy product candidates.

“Recent and emerging evidence suggests that an islet cell transplant may be able to provide the equivalent of a functional cure for some people with diabetes. Several islet cell programs for T1D have reached phase 1 clinical trials, but to our knowledge, the manufacturing process required to supply sufficient material for a meaningful portion of the addressable patient population is a challenge that remains unsolved,” said Brian M. Culley, Lineage CEO. “By building upon our recent GMP manufacturing success, we believe we have a compelling opportunity to try and reduce-to-practice an islet cell production system, capable of supporting doses in the hundreds of millions of cells per eligible patient. Our initial goal for this program is to demonstrate this capability with one of our proprietary cell lines, which parenthetically is the third cell line for which we have generated a unique master cell bank at our in-house facility. If successful, we next would seek to demonstrate system compatibility with an internally- or externally-sourced hypo-immune cell line, suitable to support a clinical campaign in T1D. Importantly, we believe we can not only reach an initial feasibility decision on this initiative with a fairly modest investment, but also apply any relevant insights or improvements to our other transplant programs, including programs we may launch in the future. Overall, if we are successful in developing a commercially-viable production modality for islet cells, we believe it will create a compelling product profile, as well as provide options to license this technology to a partner or enter the diabetes field directly.”

About Type 1 Diabetes (T1D)

Type 1 diabetes (T1D) is a chronic autoimmune condition in which the body’s immune system mistakenly attacks and destroys the insulin-producing beta cells in the pancreas. As a result, people with T1D are unable to produce insulin, a hormone essential for regulating blood sugar levels. This leads to high blood glucose, which can cause serious health complications if not managed properly. T1D is usually diagnosed in children, teens, or young adults, but it can develop at any age. Unlike type 2 diabetes, T1D is not caused by lifestyle factors and cannot be prevented. Management requires lifelong insulin therapy through injections or a pump, along with careful monitoring of blood sugar, diet, and physical activity. According to Breakthrough T1D, the leading global type 1 diabetes research and advocacy organization, there are more than 9.5 million people living with type 1 diabetes around the world, and it is one of the fastest growing, noncommunicable, chronic health conditions on the planet.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing allogeneic, or “off the shelf”, cell therapies for serious neurological and ophthalmic conditions. 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 ® cell therapy, 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 in development under a collaboration with William Demant Invest A/S 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 under a gene editing partnership. 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. In some cases, forward-looking statements, 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,” “goal,” “suggest,” or the negative version of these words and similar expressions. Such forward-looking statements include, but are not limited to, statements relating to: Lineage’s ability to apply its manufacturing capabilities to establish a production modality that can address the issues of large-scale production of islet cells, and that such capability can produce doses of hundreds of millions of cells per patient; the potential application of any such production modality achievements to a hypo-immune cell line that is suitable to support a clinical T1D program and/or any other current or future transplant programs; the ability to reach an initial feasibility decision with a fairly modest investment; and that any islet cell product candidate that we produce will have a compelling product profile. 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’s development activities of islet cells may not commence, progress or be completed as expected due to many factors within and outside of our control; that positive findings in early nonclinical studies of a TID product candidate may not be predictive of success in subsequent studies of that candidate; that the ongoing Israeli regional conflict 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; that Lineage may not be able to manufacture sufficient quantities of its product candidates in accordance with current good manufacturing practice; 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. 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 subsequent reports, which are available on the SEC's website at www.sec.gov. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. Lineage undertakes no obligation to update any forward-looking statement 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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